Problem formulation for gene drive organisms

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Abstract

Problem formulation is a central concept to risk analysis of genetically modified organisms (GMOs) and provides a structured mechanism whereby risks from GMOs can be identified and evaluated.

There has been significant discussion about the potential issues raised by the creation of GMOs with engineered gene drives and whether they should be regulated and assessed in the same way as other GMOs. This is due to the potential to 'drive' a trait into a sexually reproducing population at a higher than expected rate, the uncertainty regarding potential adverse outcomes and whether current tools for environmental risk assessment are adequate.

Although much of the discussion has been on the use of genes drives to control disease transmission by mosquitoes, some of the proposed applications of gene drive technology in Australia relate to biocontrol of pest animals. The Australian gene technology legislation requires that any work with GMOs containing a functional engineered gene drive will require a specific case-by-case evaluation of the risks and specific risk management of activities with these organisms. This assessment permits information gathering as well as monitoring of the progress of research in this new area. Case-by-case evaluation will consider any risk-mitigation measures including molecular approaches (e.g split drives, daisy drives), genetic isolation (synthetic target or target only present in a sub-population), environmental isolation or physical containment.

This presentation will outline our experience of how the problem formulation approach has been applied to assess experimental work in laboratory containment with mice, Drosophila and plant pathogenic fungi containing engineered gene drives. It will then focus on how the problem formulation approach could be used in risk assessment of GMOs containing engineered gene drives for use outside of a laboratory setting.

Key words: regulation, gene drives, GMO, risk assessment