Regulation and risk assessment of new technologies

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Abstract

There is much discussion about a variety of new technologies as to whether they are different from the 'classical' gene technology and whether they should be regulated and assessed in the same way.

In Australia, the Gene Technology Regulator (the Regulator) is responsible for authorizing work with GMOs, including contained work in labs, use of GMOs as therapeutics and the release of GMOs into the environment. The Regulator's decisions must be based on an assessment of whether any risks to people or the environment can be managed. The range and complexity of applications to work with GMOs, and the technologies employed to create these organisms has increased over time. These include an increase in the number of clinical trials involving GMOs as vaccines, gene therapies and cancer treatments.

A technical review of the Gene Technology Regulations in 2019 clarified which technologies were regulated and excluded gene edited organisms created using SDN-1 from regulation as GMOs. A broader independent review of the gene technology scheme commenced in 2017 and has recommended further amendments to ensure that legislation can keep pace with developments in gene technology. In general, the proposed new model involves risk tiering to ensure proportionate regulation and assessment of modified organisms according to the risk that they pose rather than excluding them from GMO regulation.

Key words: regulation, gene editing, GMO