



Fidge v Pfizer

1. Dr Fidge v Pfizer and Moderna, Federal Court, Australia

2. Dr Fidge seeks an injunction against Pfizer and Moderna

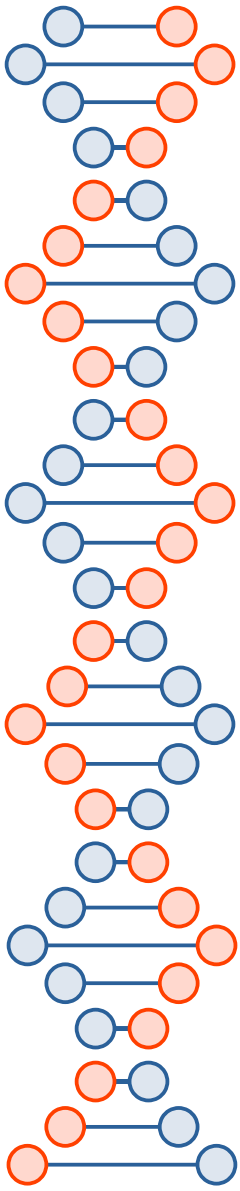
3. For dealing with GMOs

4. Without the necessary licence

The Australian Case

LNP-**mRNA** complex = organism capable of transferring genetic material through retroposition

LNP-**DNA** complex = organism capable of transferring genetic material in multiple ways

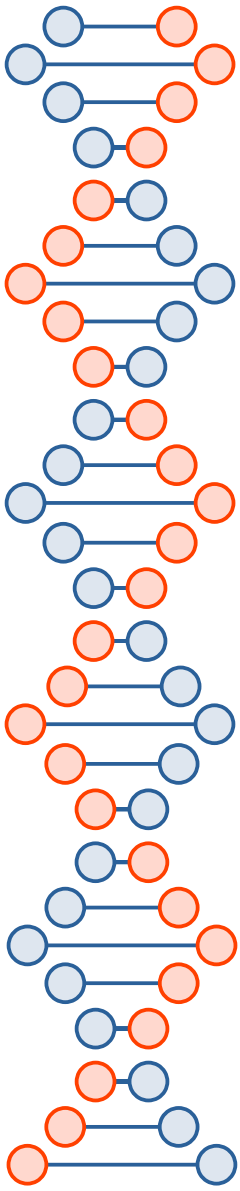


Gene Technology Act 2000

S 10 Definitions:

genetically modified organism means:

(a) an organism that has been modified by gene technology; or



Gene Technology Act 2000

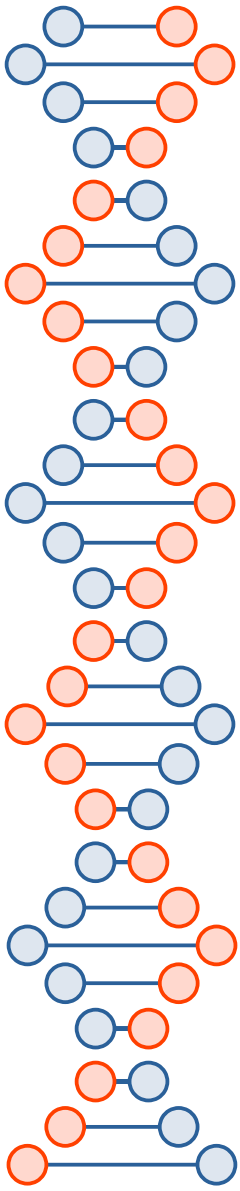
S 10 Definitions:

organism means any biological entity that is:

(a) viable; or

(b) capable of reproduction; or

(c) capable of transferring genetic material.

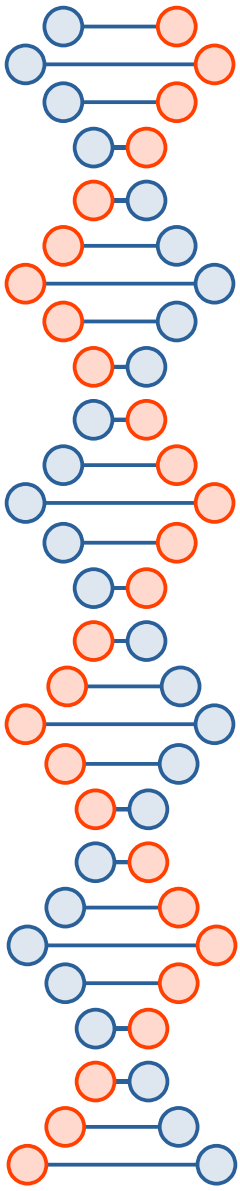


Gene Technology Act 2000

S 10 Definitions:

gene technology means any technique for the modification of genes or other genetic material.

The LNP-modified RNA and LNP-DNA complexes fulfill the legal definitions





Gene Technology Act 2000

S 10. Definitions

deal with, in relation to a GMO, means the following:

- (a) conduct experiments with the GMO;*
- (b) make, develop, produce or manufacture the GMO;*
- (c) breed the GMO;*
- (d) propagate the GMO;*
- (e) use the GMO in the course of manufacture of a thing that is not the GMO;*
- (f) grow, raise or culture the GMO;*
- (g) import the GMO;***
- (h) transport the GMO;***
- (i) dispose of the GMO;***

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).



Gene Technology Act 2000

Section 40 - A person who deals, must apply for a licence

40 Person may apply for a licence

- (1) A person may apply to the Regulator for a licence authorising specified dealings with one or more specified GMOs by a person or persons.*



Gene Technology Act 2000

Section 32 – Failure to do so is a serious criminal offence

32 Person not to deal with a GMO without a licence

(1) A person commits an offence if:

- (a) the person deals with a GMO, knowing that it is a GMO; and*
- (b) the dealing with the GMO by the person is not authorised by a GMO licence, and the person knows or is reckless as to that fact; and*
- (c) the dealing with the GMO is not specified in an emergency dealing determination, and the person knows or is reckless as to that fact; and*
- (d) the dealing is not a notifiable low risk dealing, and the person knows or is reckless as to that fact; and*
- (e) the dealing is not an exempt dealing, and the person knows or is reckless as to that fact; and*
- (f) the dealing is not included on the GMO Register, and the person knows or is reckless as to that fact.*



Gene Technology Act 2000

Section 32 – *cont*

Note: Chapter 2 of the Criminal Code sets out the general principles of criminal responsibility.

- (2) *An offence under subsection (1) is punishable on conviction by whichever of the following applies:*
- (a) *in the case of an aggravated offence— imprisonment for 5 years or 2,000 penalty units;*
 - (b) *in any other case— imprisonment for 2 years or 500 penalty units.*

Note: Section 38 defines aggravated offence.



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