Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator



Kylie Tattersall
Evaluation Section
October 2026

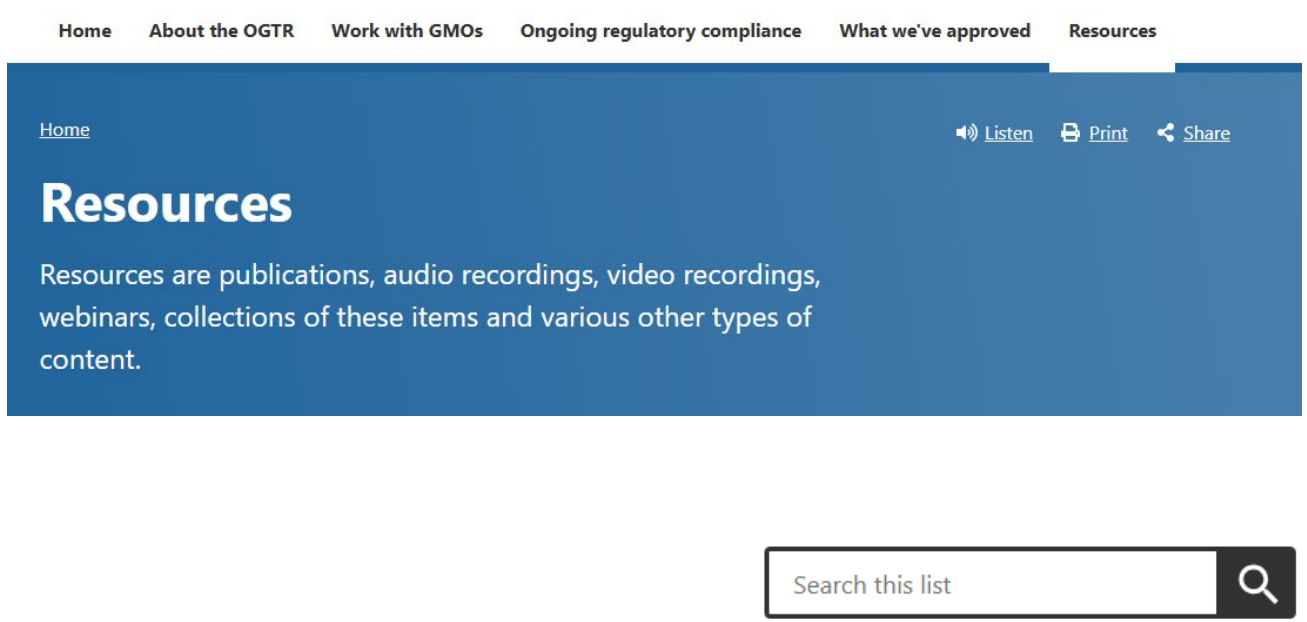
Factsheets/Guidance/Information

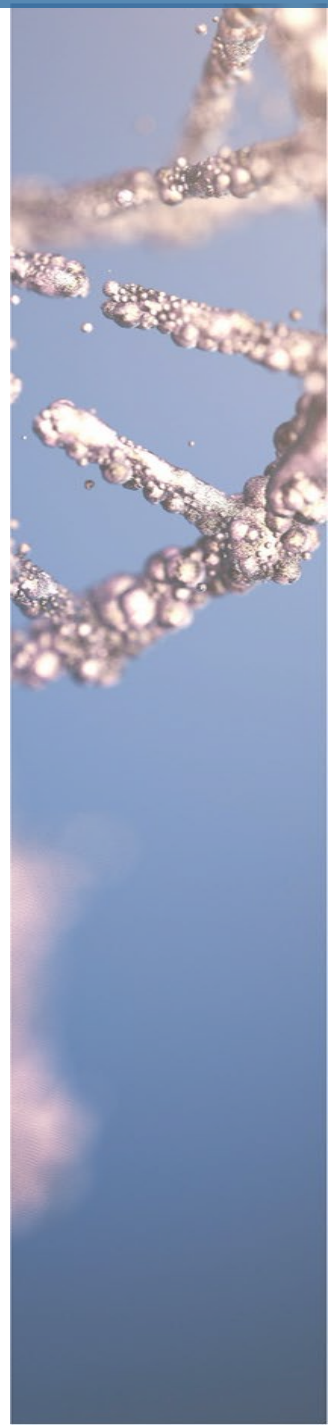
Resource type

- [ ] Collection (14)
- [ ] Publication (287)

Publication type

- [ ] Report (64)
- [ ] Fact sheet (51)
- [ ] Form (41)
- [ ] Guidelines (38)
- [ ] Meeting communique (27)
- [ ] Biology document (22)
- [ ] Framework / protocol (17)
- [ ] Statement (17)
- [ ] Policy (10)



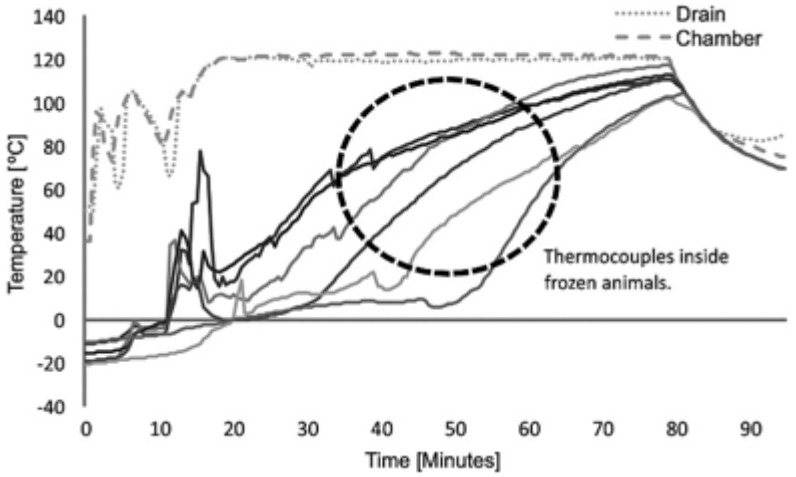


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Load Validation Profile Factsheet

(for autoclaves)

- PC3 and PC4 guidelines
- Proposed in PC2 revised guidelines
- Provides scientific rationale
- Guidance
  - Load types
  - Probe placement
  - Testing frequency

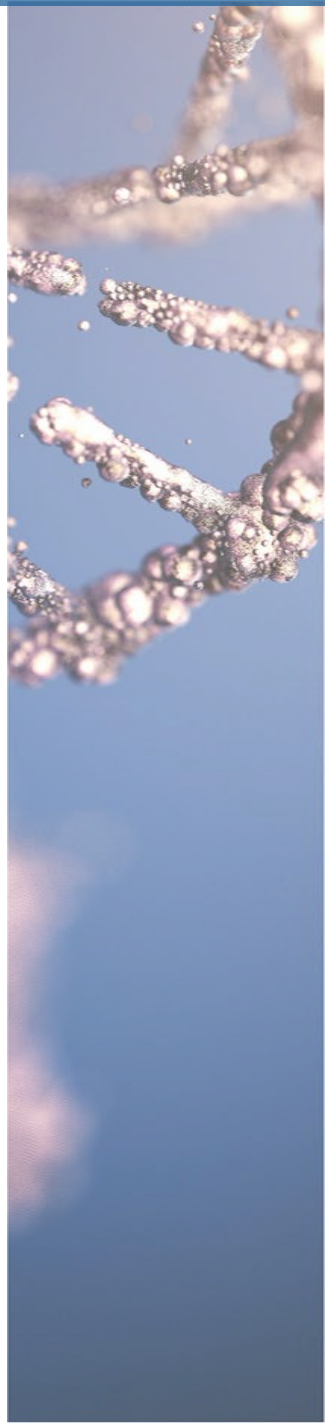


Alternative Facility and TSD requirements for self-amplifying mRNA

- Venezuelan equine encephalitis virus (VEEV) = RG3 → PC3
- TC-83 strain of VEEV – highly attenuated
- saRNA – unable to form infectious viral particles

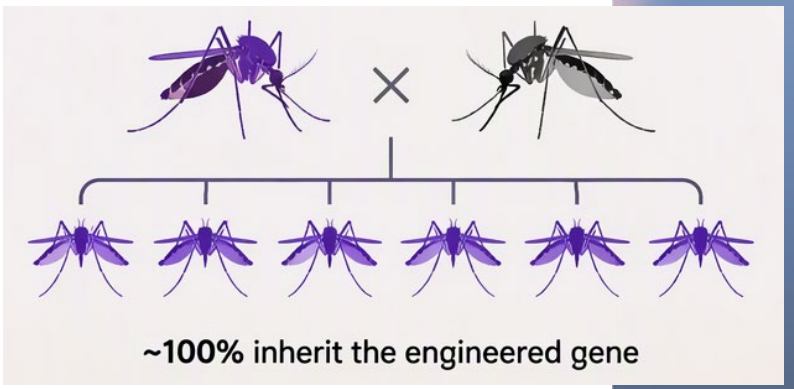
Regulator decision:

- NLRDs involving saRNA derived from VEEV TC-83 strain at volumes of ≤25 L that meet criteria specified in Sch 3, Part 2.1(d)
  - PC2 facilities (not PC2 plant) – must refer to **FAC-022**
  - TSDs for PC2 GMOs – must refer to **TSD-018**



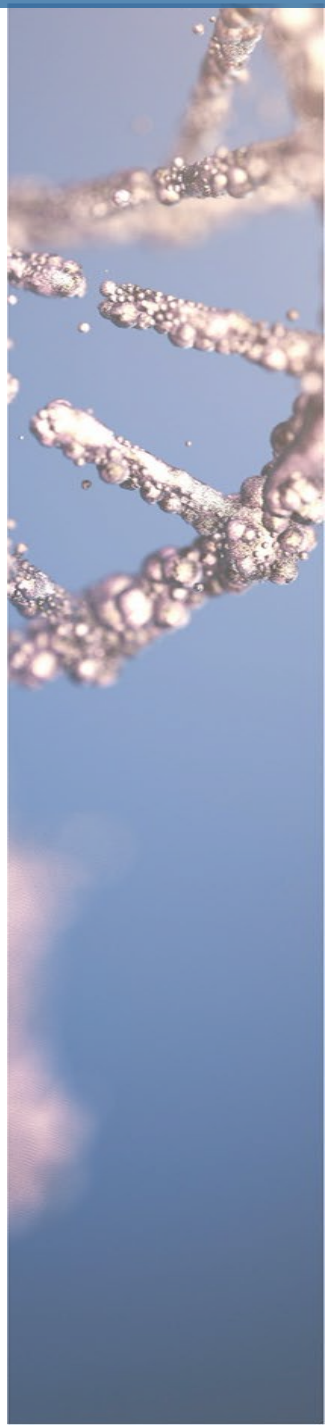
GMOs containing Gene Drives

- Risk assessment approach for the environmental release of GMOs containing engineered gene drives
- National gene drive policy guide published
- All work with GM gene drive organisms requires licence
- Uncertainties for environmental release
- Standard approach (RAF)
    - Mathematical modelling
    - Efficacy data



Other key factsheets/guidance

- Overview of the status of organisms modified using gene editing and other new technologies
- Financial suitability requirements for licence applications or variations
- OGTR Online Services Portal - Registration Guide, FAQs, MyID
- Construction, repair, and maintenance work in a low-level certified facility

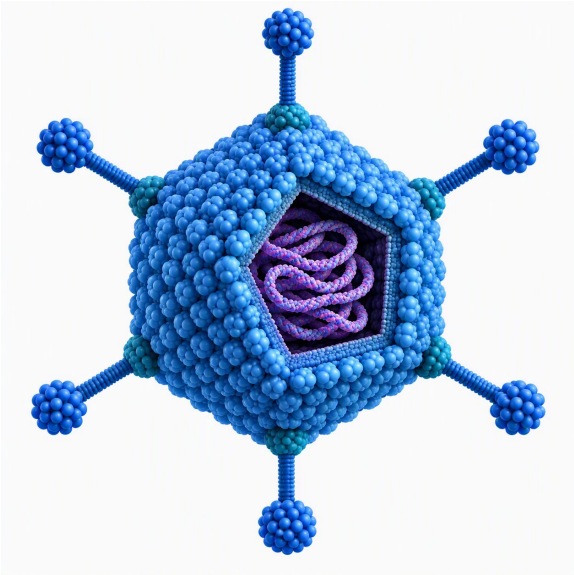


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Guidance on the classification of contained dealings with viral vectors

Key decision points:

- Risk grouping
- Replication competency
- Retrovirus or not
- Harmful or pathogenic
- Transduce cells
- *In vitro* vs *in vivo*



Guidance on the classification of contained dealings with viral vectors (cont)

Replication defective non-retroviral vectors			
Viral vector type	**Characteristics of donor nucleic acid, donor organism or modification**	***In vitro*[1]**	***In vivo***
Any	toxin or uncharacterised gene from toxin producing organism	DNIR, S3 p3.1 (a), (b) or (c)	
	genes whose expressed products are likely to increase the capacity of the viral vector to induce an autoimmune response	DNIR, S3 p3.1 (h)	
	creates novel replication competent virus with increased capacity to cause harm (e.g: new potential host species or mode of transmission; or increased virulence or transmissibility)	DNIR, S3 p3.1 (i)	
	can modify an organism so as to increase the likelihood of inheritance of particular nucleotide sequence(s) (i.e. create an engineered gene drive)	DNIR, S3 p3.1 (s)	
Risk Group 4 virus[2]	any	DNIR, S3 p3.1 (p)	
Risk Group 3 virus[2]	any	DNIR, S3 p3.1 (q) if not in an appropriate PC3 facility	
Unable to transduce human cells (and not Risk Group 3 [2])	unlikely to increase capacity to cause harm; cultures used are ≤ 25 L	Exempt, S2 p1 item 4	NLRD, S3 p2.1 (i)
	unlikely to increase capacity to cause harm; cultures used are > 25 L	NLRD, S3 p2.1 (f)	N/A
	may increase capacity to cause harm; uncharacterised nucleic acid from a pathogen	NLRD, S3 p2.1 (e)	NLRD, S3 p2.1 (i)
Able to transduce human cells:	does not confer an oncogenic modification or immunomodulatory effect in humans; not a toxin	NLRD, S3 p1.1 (c)	NLRD, S3 p2.1 (k)

Is a DIR or DNIR licence required?

Key points:

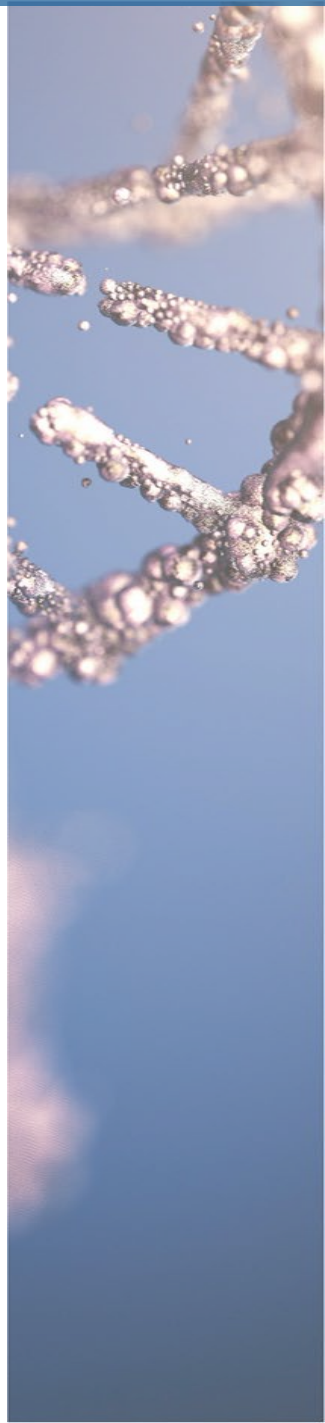
- Released into the environment
- Certified facility
- Enclosed system
- Contained transport
- Shed or excreted from a person/animal
- Mode of administration to a person/animal


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Licence for dealings involving an intentional release of a GMO into the environment

What is Immunomodulatory effect?

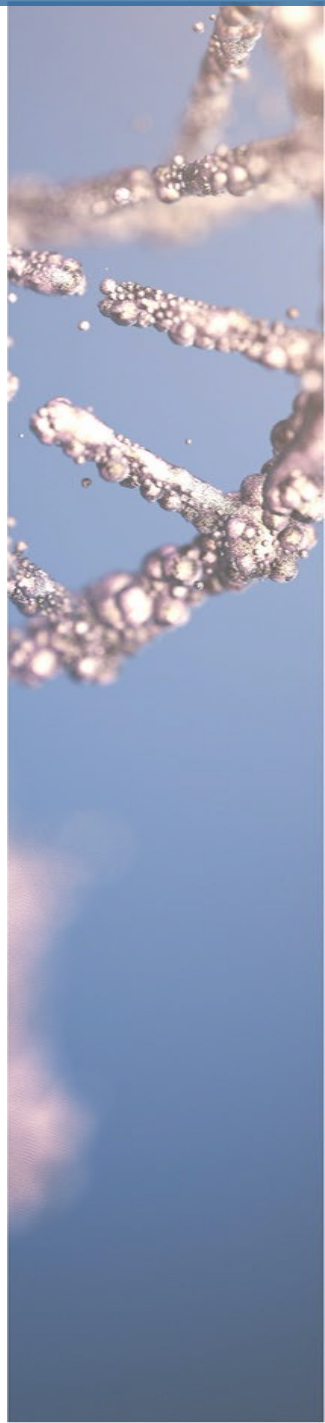
- Proteins, nucleic acid sequences or other molecules which either up-regulate or down-regulate the normal host immune response following exposure to an antigen
- Includes cytokines, growth factors, RNAi and deletions influencing immune regulation
- Not expression of antigens/epitopes that induce a normal host immune response



How should clinical trial samples containing GMOs be handled?

- Licence may specify no conditions apply to samples, e.g.:
  - considered to contain no/minimal GMOs eg urine
  - containing GMOs and time period e.g. blood, after 7 days
  - reasonably expected to not contain GMO (justification)
- Conditions – containment, not compromise health & safety, minimise exposure
- Accredited pathology lab consistent with these conditions
- TSDs, IATA or licence conditions

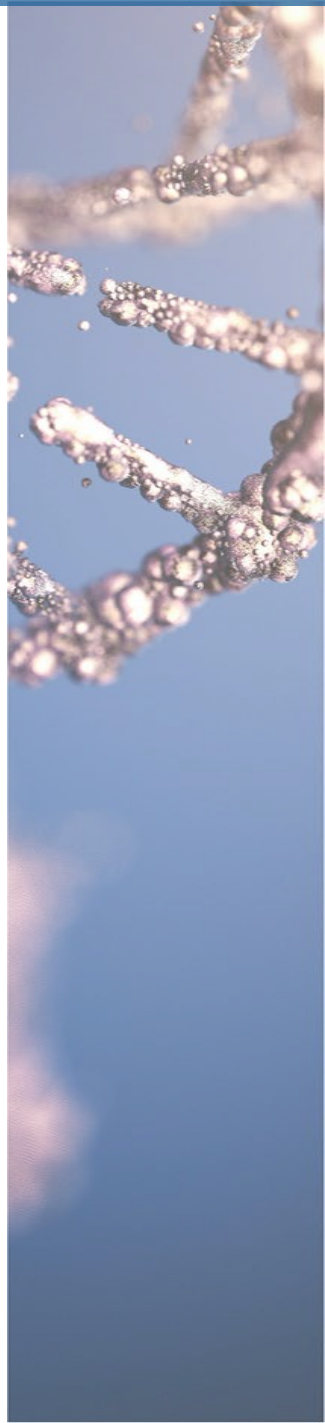
❖ but read licence – depends on nature of GMO/samples



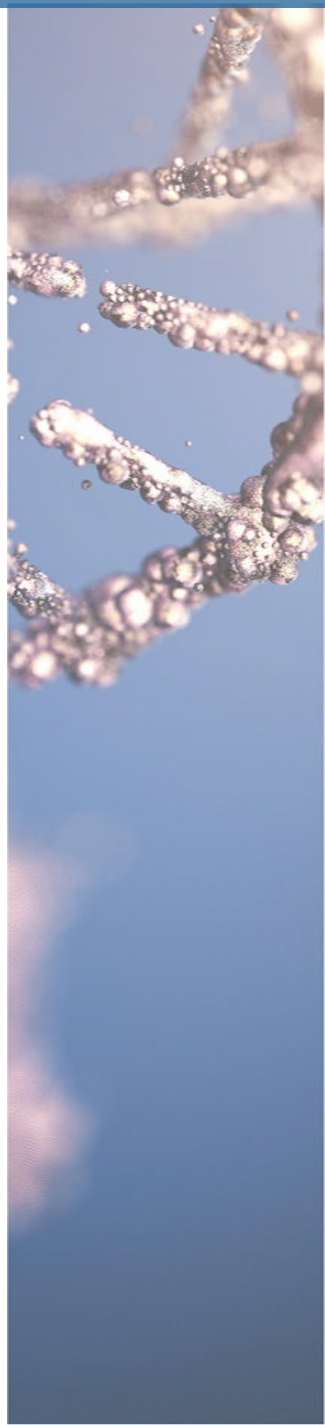
What are the roles/responsibilities when certified facilities are leased/shared?

- Certification holder is responsible

- Considerations:
  - Importance of internal governance arrangements
  - Oversite of all work conducted and who is working there
  - Use of agreements
  - Record keeping




Questions?



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