Guidance flowchart for the classification of contained dealings with viral vectors
according to the Gene Technology Regulations 2001 as amended *

parent virus meets criteria for Risk Group 4 microorganism in AS/NZS 2243.3:2010

Yes → DNIR 3.1 (p)

No

→ genetic modification impairs treatment of disease caused by virus / viral vector

Yes → DNIR 3.1 (o)

No

→ virus / viral vector is being introduced into a human

Yes → DNIR 3.1 (n)

No

→ genetic modification may produce a novel replication competent virus

Yes → DNIR 3.1 (i)

No

→ genetic modification may induce an autoimmune response

Yes → DNIR 3.1 (h)

No

→ genetic modification may result in the production of a toxin

Yes → DNIR 3.1 (a), (b) or (c)

No

Go to virus characteristics

* Effective from 1 September 2011, incorporating amendments up to the Gene Technology Amendment Regulations 2011 (No. 1). This table provides guidance only and does not constitute legal advice. Users must refer to the complete applicable conditions and exclusions in the Gene Technology Regulations 2001, as amended.

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Virus characteristics

vector is a replication competent virus

No

Yes

Go to 1 – Replication competent viruses

Yes

Go to Replication competent viruses

No

Genetic modification restores replication competence

Yes

Go to Replication competent viruses

No

vector is a retrovirus (including lentivirus)

Yes

Go to Replication defective retroviruses

No

Go to Replication defective non-retroviruses
Replication competent viruses

- Virus is non-pathogenic plant virus or *Baculovirus* (ACNPV)
  - Yes → modification involves a pathogenic determinant
  - No → NLRD 2.1 (c) in vivo
  - No → NLRD 2.1 (c) in vitro

- May confer an oncogenic modification or have an immunomodulatory effect in humans
  - Yes → DNIR 3.1 (e)
  - No → NLRD 2.1 (c) exempt in vitro
  - NLRD 2.1 (f) >25L per vessel

- Modification involves a pathogenic determinant
  - Yes → virus is a pathogen
  - No → DNIR 3.1 (g)

- Virus is a pathogen
  - Yes → NLRD 2.1 (d)
  - No → NLRD 2.1 (c)
Replication defective retroviruses

- Vector can transduce human cells
  - Yes → in vitro dealings only
  - No → NLRD 2.1 (i)

- in vitro dealings only
  - Yes → modification involves a pathogenic determinant
  - No → exempt

- modification involves a pathogenic determinant
  - Yes → NLRD 2.1 (e)
  - No → NLRD 2.1 (f) >25L per vessel

- accessory genes are present and vector is not self-inactivating
  - Yes → may confer an oncogenic modification or have an immunomodulatory effect in humans
  - No → DNIR 3.1 (d) & (j)

- may confer an oncogenic modification or have an immunomodulatory effect in humans
  - Yes → DNIR 3.1 (d) & (j)
  - No → NLRD 2.1 (m)

- in vitro dealings only
  - Yes → NLRD 2.1 (l)
  - No → DNIR 3.1 (d) & (j)
Replication defective non-retroviruses

- Vector can transduce human cells
  - Yes
  - In vitro dealings only
    - Yes
      - Modification involves a pathogenic determinant
        - Yes
      - NLRD 2.1 (e)
    - No
      - Exempt
        - NLRD 2.1 (f)
          - >25L per vessel
  - No
    - NLRD 2.1 (i)

- In vitro dealings only
  - Yes
    - May confer an oncogenic modification or have an immunomodulatory effect in humans
      - Yes
      - DNIR 3.1 (d)
      - No
      - DNIR 3.1 (k)
  - No

- May confer an oncogenic modification or have an immunomodulatory effect in humans
  - Yes
    - Human adenovirus or Adeno associated virus
      - Yes
      - NLRD 1.1 (c)
      - No
      - NLRD 2.1 (j)