



Guidance tables for the classification of contained dealings with viral vectors

according to the Gene Technology Regulation 2001 as amended *

Viral vector type	Characteristics of donor nucleic acid or donor organism	<i>In vitro</i>	<i>In vivo</i>
Replication competent vectors			
Non-pathogenic plant viral vector or Baculovirus (<i>Autographa californica nuclear polyhedrosis virus</i>), polyhedrin minus	not a pathogenic determinant and not a toxin and cultures used are ≤ 25 L	Exempt, S2 p1 item 4	PC2 NLRD, S3, p2.1
	not a pathogenic determinant and not a toxin and cultures used are > 25 L	PC2 NLRD, S3 p2.1	N/A
	pathogenic determinant	PC2 NLRD, S3 p2.1	DNIR, S3 p3.1 (g)
	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 virus/viral vector to induce an autoimmune response	DNIR, S3 p3.1 (h)	
	creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	DNIR, S3 p3.1 (i)	
All other replication competent viruses (including Avipox vectors)	not a pathogenic determinant and not a toxin and not an oncogenic modification and not immunomodulatory in humans	PC2 NLRD, S3 p2.1 (c) or (d)	
	toxin or an uncharacterised gene from toxin producing organism	DNIR, S3 p3.1 (a), (b) or (c)	
	oncogenic modification or immunomodulatory in humans	DNIR, S3 p3.1 (e)	
	pathogenic determinant	DNIR, S3 p3.1 (f) or (g)	
	virus satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 4	DNIR, S3 p3.1 (p)	
	genes whose expressed products are likely to increase the capacity of the virus/viral vector to induce an autoimmune response	DNIR, S3 p3.1 (h)	
	creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	DNIR, S3 p3.1 (i)	
	drug resistance genes or other nucleic acid that could impair practical treatment of any disease or abnormality caused by the virus/viral vector	DNIR, S3 p3.1 (o)	

S = Schedule

exempt = exempt dealing

PC1 = Physical containment level 1

PC2 = Physical containment level 2

p = Part (of the Regulations)

NLRD = notifiable low risk dealing

DNIR = dealing not involving intentional release

* 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.

Guidance on classification of contained dealings with viral vectors

according to the *Gene Technology Regulations 2001* as amended *

Viral vector type	Characteristics of donor nucleic acid or donor organism	In vitro	In vivo
Replication defective vectors - retroviral (includes lentiviruses)¹			
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 virus/viral vector to induce an autoimmune response	DNIR, S3 p3.1 (h)	
	creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	DNIR, S3 p3.1 (i)	
	drug resistance genes or other nucleic acid that could impair practical treatment of any disease or abnormality caused by the viral vector	DNIR, S3 p3.1 (o)	
Unable to transduce human cells	not a pathogenic determinant and not a toxin and cultures used are ≤25 L	Exempt, S2 p1 item 4	PC2 NLRD, S3 p2.1 (i)
	not a pathogenic determinant and not a toxin and cultures used are > 25 L	PC2 NLRD, S3 p2.1 (f)	N/A
	pathogenic determinant	PC2 NLRD, 2.1 (e)	PC2 NLRD, S3 p2.1 (i)
Able to transduce human cells: Self inactivating and/or accessory genes are not present ²	not a toxin and not an oncogenic modification and not immunomodulatory in humans	PC2 NLRD, S3 p2.1 (l)	PC2 NLRD, S3 p2.1 (m)
	oncogenic modification or immunomodulatory in humans	PC2 NLRD, S3 p2.1 (l)	DNIR, S3 p3.1 (d) & (j)
Able to transduce human cells not self-inactivating and accessory genes are present	not a toxin and not an oncogenic modification and not immunomodulatory in humans	DNIR, S3 p3.1 (j)	
	oncogenic modification or immunomodulatory in humans	DNIR, S3 p3.1 (d) & (j)	

¹ Replication defective retroviral vectors must include safety features to reduce the likelihood of recombination leading to replication competence being regained, including that all viral genes must be removed from the retroviral vector so that it cannot replicate or assemble into a virion without these functions being supplied in trans, and that viral genes needed for virion production must be expressed from independent, unlinked loci with minimal sequence overlap

² Only gagpol and env (and rev if a lentiviral vector) present in the packaging system

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Viral vector type	Characteristics of donor nucleic acid or donor organism	In vitro	In vivo
Replication defective vectors – non-retroviral			
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 altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	DNIR, S3 p3.1 (i)	
	virus satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 4	DNIR, S3 p3.1 (p)	
Unable to transduce human cells	not a pathogenic determinant and not a toxin and cultures used are ≤ 25 L	Exempt, S2 p1 item 4	PC2 NLRD, S3 p2.1 (i)
	not a pathogenic determinant and not a toxin and cultures used are > 25 L	PC2 NLRD, S3 p2.1 (f)	N/A
	pathogenic determinant	PC2 NLRD, S3 p2.1 (e)	PC2 NLRD, S3 p2.1 (i)
Able to transduce human cells: <i>Human adenovirus</i> or <i>Adeno associated virus</i>	not a toxin and not an oncogenic modification and not immunomodulatory in humans	PC1 NLRD, S3 p1.1 (c)	PC2 NLRD, S3 p2.1 (k)
	oncogenic modification or immunomodulatory in humans	PC2 NLRD, S3 p2.1 (j)	DNIR, S3 p3.1 (d)
	drug resistance genes or other nucleic acid that could impair practical treatment of any disease or abnormality caused by the viral vector	DNIR, S3 p3.1 (o)	
Able to transduce human cells: all other viruses	not a toxin and not an oncogenic modification and not immunomodulatory in humans	PC2 NLRD, S3 p2.1 (j)	PC2 NLRD, S3 p2.1 (k)
	oncogenic modification or immunomodulatory in humans	PC2 NLRD, S3 p2.1 (j)	DNIR, S3 p3.1 (d)
	drug resistance genes or other nucleic acid that could impair practical treatment of any disease or abnormality caused by the viral vector	DNIR, S3 p3.1 (o)	

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