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

Guidance tables for the 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 competent vectors			
Non-pathogenic plant viral vector or Baculovirus (*Autographa californica nuclear polyhedrosis virus*), 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 (c)
	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)	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

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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[2]	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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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 – 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: *Human adenovirus* or *Adeno associated virus*	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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