Guidance on the classification of contained dealings with viral vectors*

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: *Human adenovirus* or *Adeno associated virus*	does not confer an oncogenic modification or immunomodulatory effect in humans; not a toxin	NLRD, S3 p1.1 (c)	NLRD, S3 p2.1 (k)
	confers an oncogenic modification or immunomodulatory effect in humans; not a toxin	NLRD, S3 p2.1 (j)	DNIR, S3 p3.1 (d)
	would impair practical treatment of any disease or abnormality caused by the virus (e.g. drug resistance)	DNIR, S3 p3.1 (o)	
Able to transduce human cells: all other viruses	not a toxin	NLRD, S3 p2.1 (j)	NLRD, S3 p2.1 (k)
	oncogenic modification or immunomodulatory in humans	NLRD, S3 p2.1 (j)	DNIR, S3 p3.1 (d)
	would impair the practical treatment of any disease or abnormality caused by the virus (e.g. drug resistance)	DNIR, S3 p3.1 (o)	

DNIR = dealing not involving intentional release, exempt = exempt dealing, NLRD = notifiable low risk dealing; p = Part (of the Regulations); S = Schedule (of the Regulations)

[1] In cell or tissue culture, as packaged virions without a host, or naked vector nucleic acid (if the nucleic acid can produce infectious particles when introduced into a suitable host cell).

[2] Unmodified parent virus satisfies the criteria in AS/NZS 2243.3:2010 for classification in the indicated Risk Group.

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Guidance on the classification of contained dealings with viral vectors*

Replication defective* 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 virus/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)	
	would impair practical treatment of any disease or abnormality caused by the viral vector (e.g. drug resistance)	DNIR, S3 p3.1 (o)	
	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)	
Unable to transduce human cells	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 (e.g. pathogenic determinant); not a toxin	NLRD, S3 2.1 (e)	NLRD, S3 p2.1 (i)
Able to transduce human cells[3]: Self inactivating **and/or** accessory genes **not** present	does not confer an oncogenic modification or immunomodulatory effect in humans; not a toxin	NLRD, S3 p2.1 (l)	NLRD, S3 p2.1 (m)
	confers an oncogenic modification or immunomodulatory effect in humans; not a toxin	NLRD, S3 p2.1 (l)	DNIR, S3 p3.1 (d) & (j)
Able to transduce human cells: not self inactivating **and** accessory genes **are** present	does not confer an oncogenic modification and not immunomodulatory effect in humans; not a toxin	DNIR, S3 p3.1 (j)	
	oncogenic modification or immunomodulatory in humans	DNIR, S3 p3.1 (d) & (j)	
Risk Group 4 virus[2]	any	DNIR, S3 p3.1 (p)	

[3] As well as including one of the indicated safety features to reduce the likelihood of recombination leading to replication competence being regained, additional requirements apply, including that all viral genes must be removed from the vector and only *gagpol*, *env rev* viral sequences may be present in the packaging system.

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Guidance on the classification of contained dealings with viral vectors*

Replication competent vectors			
Viral vector type	**Characteristics of donor nucleic acid or donor organism**	***In vitro*[1]**	***In vivo***
Any	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)	
Non-pathogenic plant viral vector or Baculovirus (polyhedrin minus forms of *Autographa californica nuclear polyhedrosis virus*)	unlikely to increase capacity to cause harm; cultures used are ≤ 25 L	Exempt, S2 p1 item 4	NLRD, S3 p2.1 (c)
	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	NLRD, S3 p2.1 (e)	DNIR, S3 p3.1 (f) & (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 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)	
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	
All other replication competent viruses	not a pathogenic determinant and not a toxin and not an oncogenic modification and not immunomodulatory in humans	NLRD, S3 p2.1 (c) or (d)	
	toxin or an uncharacterised gene from toxin producing organism	DNIR, S3 p3.1 (a), (b) or (c)	
	confers an oncogenic modification or immunomodulatory effect in humans	DNIR, S3 p3.1 (e)	
	pathogenic determinant or may otherwise increase capacity of virus to cause harm	DNIR, S3 p3.1 (f) or (g)	
	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 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)	
	would impair practical treatment of any disease or abnormality caused by the virus (e.g. drug resistance)	DNIR, S3 p3.1 (o)	

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