



Guidance on classification of contained dealings with viral vectors

according to the *Gene Technology Regulations 2001* and the *Gene Technology Amendment Regulations 2006* *

Viral vector type	Host	Exempt system?	Characteristics of donor nucleic acid or donor organism	Applicable regulation *	Class of dealing
Replication defective vectors					
1) Not retroviral					
• unable to transduce human cells	tissue culture	yes	non -pathogenic / -toxic (may be oncogenic) (if > 10 L cultures, then becomes)	S2 p1 item 4 (S3 p1 (f))	exempt (NLRD)
			pathogenic	S3 p1 (e)	NLRD
			toxic	S3 p2 (a), (b) or (c)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p2 (h)	DNIR
• able to transduce human cells (eg Ad5)	tissue culture	yes	Non -pathogenic / -oncogenic / -toxic (if > 10 L cultures, then becomes)	S2 p1 item 4 (S3 p1 (f))	exempt (NLRD)
			pathogenic / oncogenic	S3 p1 (e)	NLRD
			toxic	S3 p2 (a), (b) or (c)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p2 (h)	DNIR
• unable <i>OR</i> able to transduce human cells	whole animal / plant	no	non -toxic / -oncogenic etc (see cells below)	S3 p1 (c) or (d)	NLRD
			toxic	S3 p2 (a), (b) or (c)	DNIR
			oncogenic / immuno-modulatory / cytokine / leads to cell proliferation	S3 p2 (d)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p2 (h)	DNIR

exempt = exempt dealing NLRD = notifiable low risk dealing DNIR = dealing not involving intentional release S = Schedule, p = Part

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Replication defective vectors					
2) Retroviral					
<ul style="list-style-type: none"> unable to transduce human cells (Note: same classification as for non-retroviral defective vectors unable to transduce human cells in tissue culture, above)	tissue culture	yes	non -pathogenic / -toxic (may be oncogenic) (if > 10 L cultures, then becomes)	S2 p1 item 4 (S3 p1 (f))	exempt (NLRD)
			pathogenic	S3 p1 (e)	NLRD
			toxic	S3 p2 (a), (b) or (c)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p2 (h)	DNIR
<ul style="list-style-type: none"> able to transduce human cells 	tissue culture	no	non-toxic (may be pathogenic, oncogenic)	S3 p1 (i)	NLRD
			toxic	S3 p2 (a), (b) or (c)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p2 (h)	DNIR
<ul style="list-style-type: none"> unable <i>OR</i> able to transduce human cells (Note: same classification as non-retroviral defective vectors in animals, above)	whole animal / plant	no	non -toxic / -oncogenic etc (see cells below)	S3 p1 (c) or (d)	NLRD
			toxic	S3 p2 (a), (b) or (c)	DNIR
			oncogenic / immuno-modulatory / cytokine / leads to cell proliferation	S3 p2 (d)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p2 (h)	DNIR
<ul style="list-style-type: none"> lentivirus able to transduce human cells <u>unless</u> all structural & accessory genes deleted and transcriptionally inactive 	tissue culture <i>OR</i> animal / plant	no	any (Note: if structural & accessory genes deleted and transcriptionally inactive, classify as for other defective retroviral systems above)	S3 p2 (i)	DNIR

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Replication competent vectors					
<ul style="list-style-type: none"> non-pathogenic plant viral vector 	plant tissue culture	yes	non -pathogenic / -toxic (may be oncogenic) (if > 10 L cultures, then becomes)	S2 p1 item 4 (S3 p1 (f))	exempt (NLRD)
			pathogenic	S3 p1 (e)	NLRD
			toxic	S3 p2 (a), (b) or (c)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p2 (h)	DNIR
<ul style="list-style-type: none"> Baculovirus (polyhedron minus) OR Avipox (attenuated vaccine strains) 	animal tissue culture	yes	non -pathogenic / -toxic (may be oncogenic) (if > 10 L cultures, then becomes)	S2 p1 item 4 (S3 p1 (f))	exempt (NLRD)
			pathogenic	S3 p1 (e)	NLRD
			toxic	S3 p2 (a), (b) or (c)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p2 (h)	DNIR
<ul style="list-style-type: none"> other plant or animal viruses: unable OR able to transduce human cells 	tissue culture OR whole animal / plant	no	non -pathogenic / -toxic / -oncogenic etc (see cells below)	S3 p1 (c) or (d)	NLRD
			pathogenic	S3 p2 (e)	DNIR
			toxic	S3 p2 (a), (b) or (c)	DNIR
			oncogenic / immuno-modulatory / cytokine / leads to cell proliferation	S3 p2 (d)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p2 (h)	DNIR

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