



## Guidance on classification of contained dealings with viral vectors

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

Viral vector type	Host	Exempt system?	Characteristics of donor nucleic acid or donor organism	Applicable regulation *	Class of dealing
<b>Replication defective vectors</b>					
1) Not retroviral					
• unable to transduce human cells	tissue culture	yes	non -pathogenic / -toxic / -oncogenic (if > 10 L cultures, then becomes)	S2 p1 item 4 (S3 p2 (f))	exempt (PC2 NLRD)
			oncogenic	S3 p1 (b)	PC1 NLRD
			pathogenic	S3 p2 (e)	PC2 NLRD
			toxic	S3 p3 (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	no	non -oncogenic / -toxic	S3 p1 (c)	PC1 NLRD
			oncogenic	S3 p2 (i)	PC2 NLRD
			toxic	S3 p3 (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 p3 (h)	DNIR
• unable <i>OR</i> able to transduce human cells	whole animal / plant	no	non -toxic / -oncogenic etc (see cells below)	S3 p2 (c) or (d)	PC2 NLRD
			toxic	S3 p3 (a), (b) or (c)	DNIR
			oncogenic / immuno-modulatory / cytokine / leads to cell proliferation	S3 p3 (d)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p3 (h)	DNIR

S = Schedule

p = Part (of the Regulations)

exempt = exempt dealing

NLRD = notifiable low risk dealing

PC1 = Physical containment level 1

DNIR = dealing not involving intentional release

PC2 = Physical containment level 2

\* Effective from 1 July 2007, incorporating amendments up to the *Gene Technology Amendment Regulations 2007 (No. 1)*. This table provides guidance only. 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	Host	Exempt system?	Characteristics of donor nucleic acid or donor organism	Applicable regulation *	Class of dealing
<b>Replication defective vectors</b>					
2) Retroviral					
<ul style="list-style-type: none"> <li>unable to transduce human cells</li> </ul> (Note: same classification as for non-retroviral defective vectors unable to transduce human cells in tissue culture, above)	tissue culture	yes	non -pathogenic / -toxic / -oncogenic (if > 10 L cultures, then becomes)	S2 p1 item 4 (S3 p2 (f))	exempt (PC2 NLRD)
			oncogenic	S3 p1 (b)	PC1 NLRD
			pathogenic	S3 p2 (e)	PC2 NLRD
			toxic	S3 p3 (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 p3 (h)	DNIR
<ul style="list-style-type: none"> <li>able to transduce human cells</li> </ul>	tissue culture	no	non-toxic (may be pathogenic, oncogenic)	S3 p2 (i)	PC2 NLRD
			toxic	S3 p3 (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 p3 (h)	DNIR
<ul style="list-style-type: none"> <li>unable <i>OR</i> able to transduce human cells</li> </ul> (Note: same classification as non-retroviral defective vectors in animals, above)	whole animal / plant	no	non -toxic / -oncogenic etc (see cells below)	S3 p2 (c) or (d)	PC2 NLRD
			toxic	S3 p3 (a), (b) or (c)	DNIR
			oncogenic / immuno-modulatory / cytokine / leads to cell proliferation	S3 p3 (d)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p3 (h)	DNIR
<ul style="list-style-type: none"> <li>lentivirus able to transduce human cells <u>unless</u> all structural &amp; accessory genes deleted and transcriptionally inactive</li> </ul>	tissue culture OR animal / plant	no	any (Note: if structural & accessory genes deleted and transcriptionally inactive, classify as for other defective retroviral systems above)	S3 p3 (i)	DNIR

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 July 2007, incorporating amendments up to the *Gene Technology Amendment Regulations 2007 (No. 1)*. This table provides guidance only. 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	Host	Exempt system?	Characteristics of donor nucleic acid or donor organism	Applicable regulation *	Class of dealing
<b>Replication competent vectors</b>					
<ul style="list-style-type: none"> <li>non-pathogenic plant viral vector</li> </ul>	plant tissue culture	yes	non -pathogenic / -toxic / -oncogenic (if > 10 L cultures, then becomes)	S2 p1 item 4 (S3 p2 (f))	exempt (PC2 NLRD)
			oncogenic (for vertebrate cell)	S3 P1 (b)	PC1 NLRD
			pathogenic	S3 p2 (e)	PC2 NLRD
			toxic	S3 p3 (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 p3 (h)	DNIR
<ul style="list-style-type: none"> <li>Baculovirus (polyhedron minus)</li> <li>OR</li> <li>Avipox (attenuated vaccine strains)</li> </ul>	animal tissue culture	yes	non -pathogenic / -toxic / -oncogenic (if > 10 L cultures, then becomes)	S2 p1 item 4 (S3 p2 (f))	exempt (PC2 NLRD)
			oncogenic (for vertebrate cell)	S3 P1 (b)	PC1 NLRD
			pathogenic	S3 p2 (e)	PC2 NLRD
			toxic	S3 p3 (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 p3 (h)	DNIR
<ul style="list-style-type: none"> <li>other plant or animal viruses:</li> <li>unable OR able to transduce human cells</li> </ul>	tissue culture OR whole animal / plant	no	non -pathogenic / -toxic / -oncogenic etc (see cells below)	S3 p2 (c) or (d)	PC2 NLRD
			pathogenic	S3 p3 (e) or (f)	DNIR
			toxic	S3 p3 (a), (b) or (c)	DNIR
			oncogenic / immuno-modulatory / cytokine / leads to cell proliferation	S3 p3 (d)	DNIR
			creates novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility	S3 p3 (h)	DNIR

S = Schedule

p = Part (of the Regulations)

exempt = exempt dealing

NLRD = notifiable low risk dealing

PC1 = Physical containment level 1

DNIR = dealing not involving intentional release

PC2 = Physical containment level 2

\* Effective from 1 July 2007, incorporating amendments up to the *Gene Technology Amendment Regulations 2007 (No. 1)*. This table provides guidance only. Users must refer to the complete applicable conditions and exclusions in the *Gene Technology Regulations 2001*, as amended.