



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 | <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 (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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according to the *Gene Technology Regulations 2001 as amended* *

| Viral vector type | Characteristics of donor nucleic acid or donor organism | <i>In vitro</i> | <i>In vivo</i> |
|--|--|-------------------------------|-------------------------|
| 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 *gag/pol* 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 | <i>In vitro</i> | <i>In vivo</i> |
|--|--|-------------------------------|-----------------------|
| 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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