



| <b>Replication defective non-retroviral vectors</b>  |   |   |                       |
|--|---|---|-----------------------|
| <b>Viral vector type</b>   | <b>Characteristics of donor nucleic acid, donor organism or modification</b>  | <b><i>In vitro</i><sup>1</sup></b>                      | <b><i>In vivo</i></b> |
| 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 <sup>2</sup>  | any   | DNIR, S3 p3.1 (p)                                       |                       |
| Risk Group 3 virus <sup>2</sup>  | any   | DNIR, S3 p3.1 (q) if not in an appropriate PC3 facility |                       |
| Unable to transduce human cells (and not Risk Group 3 <sup>2</sup> )                             | 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:<br><i>Human adenovirus</i><br>or<br><i>Adeno associated virus</i> | 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:   | 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)     |
| all other viruses  | 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)

<sup>1</sup> 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).

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

\* Guidance only – refer to detail in the applicable clauses of the Gene Technology Regulations 2001, as current at the time. This guidance reflects the Commonwealth Regulations incorporating amendments from Schedule 1 of the Gene Technology Amendment (2019 Measures No. 1) Regulations 2019, which commence on 8 October 2019.

## Guidance on the classification of contained dealings with viral vectors\*

| <b>Replication defective retroviral vectors</b>   |   |                                    |                         |
|---|---|------------------------------------|-------------------------|
| <b>Viral vector type</b>  | <b>Characteristics of donor nucleic acid, donor organism or modification</b>  | <b><i>In vitro</i><sup>1</sup></b> | <b><i>In vivo</i></b>   |
| 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 <sup>3</sup> :<br>Self inactivating<br><b>and/or</b><br>accessory genes<br><b>not</b> 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:<br>not self inactivating<br><b>and</b><br>accessory genes<br><b>are</b> 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 <sup>2</sup>   | any   | DNIR, S3 p3.1 (p)                  |                         |

<sup>3</sup> 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\*

| <b>Replication competent vectors</b>   |   |   |                         |
|--|---|---|-------------------------|
| <b>Viral vector type</b>   | <b>Characteristics of donor nucleic acid or donor organism</b>  | <b><i>In vitro</i><sup>1</sup></b>                      | <b><i>In vivo</i></b>   |
| 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<br>or<br>Baculovirus (polyhedrin minus forms of <i>Autographa californica nuclear polyhedrosis virus</i> ) | 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 <sup>2</sup>  | any   | DNIR, S3 p3.1 (p)                                       |                         |
| Risk Group 3 virus <sup>2</sup>  | 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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