
Part 3 Dealings that are not notifiable low risk dealings

Note 1 The following list qualifies the list in Parts 1 and 2, and is not an exhaustive list of dealings that are not notifiable low risk dealings.

Note 2 A dealing that is not a notifiable low risk dealing, or an exempt dealing, can only be undertaken by a person who is licensed, under the Act, for the dealing (see Act, section 32).

3.1 Kinds of dealings

A dealing of any of the following kinds, or involving a dealing of the following kinds, is not a notifiable low risk dealing:

- (a) a dealing (other than a dealing mentioned in paragraph 2.1 (h)) involving cloning of nucleic acid encoding a toxin having an LD₅₀ of less than 100 µg/kg;
- (b) a dealing involving high level expression of toxin genes, even if the LD₅₀ is 100 µg/kg or more;
- (c) a dealing (other than a dealing mentioned in paragraph 2.1 (h)) involving cloning of uncharacterised nucleic acid from a toxin-producing organism;
- (d) a dealing involving the introduction of a replication defective viral vector into a host not mentioned in Part 2 of Schedule 2, other than a dealing mentioned in paragraph 2.1 (i), if the donor nucleic acid:
 - (i) confers an oncogenic modification in humans; or
 - (ii) encodes a protein with immunomodulatory activity in humans;
- (e) a dealing involving a replication competent virus or viral vector, other than a vector mentioned in Part 2 of Schedule 2, if the donor nucleic acid:
 - (i) confers an oncogenic modification in humans; or
 - (ii) encodes a protein with immunomodulatory activity in humans;

- (f) a dealing involving, as host or vector, a micro-organism, if:
- (i) the micro-organism has been implicated in, or has a history of causing, disease in otherwise healthy:
 - (A) human beings; or
 - (B) animals; or
 - (C) plants; or
 - (D) fungi; and
 - (ii) none of the following sub-subparagraphs apply:
 - (A) the host/vector system is a system mentioned in Part 2 of Schedule 2;
 - (B) the donor nucleic acid is characterised and its characterisation shows that it is unlikely to increase the capacity of the host or vector to cause harm;
 - (C) the dealing is a dealing mentioned in paragraph 2.1 (g);
- Example*
- Donor nucleic acid would not comply with sub-subparagraph (B) if, in relation to the capacity of the host or vector to cause harm, it:
- (a) provides an advantage; or
 - (b) adds a potential host species or mode of transmission; or
 - (c) increases its virulence, pathogenicity or transmissibility.
- (g) a dealing involving the introduction, into a micro-organism, of nucleic acid encoding a pathogenic determinant, unless:
- (i) the dealing is a dealing mentioned in paragraph 2.1 (g); or
 - (ii) the micro-organism is a host mentioned in Part 2 of Schedule 2;
- (h) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes whose expressed products are likely to increase the capacity of the micro-organisms to induce an autoimmune response;

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- (i) a dealing involving use of a viral or viroid genome, or fragments of a viral or viroid genome, to produce a novel replication competent virus with an increased capacity to cause harm compared to the capacity of the parent or donor organism;

Example

A dealing would comply with paragraph (i) if it produces a novel replication competent virus that has a higher capacity to cause harm to any potential host species than the parent organism because the new virus has:

- (a) an advantage; or
 - (b) a new potential host species or mode of transmissibility; or
 - (c) increased virulence, pathogenicity or transmissibility.
- (j) a dealing, other than a dealing mentioned in paragraph 2.1 (l) or (m), with a replication defective retroviral vector (including a lentiviral vector) able to transduce human cells;
- (k) a dealing involving a genetically modified animal, plant or fungus that is capable of secreting or producing infectious agents as a result of the genetic modification;
- (l) a dealing producing, in each vessel containing the resultant GMO culture, more than 25 litres of that culture, other than a dealing mentioned in paragraph 2.1 (f);
- (m) a dealing that is inconsistent with a policy principle issued by the Ministerial Council;
- (n) a dealing involving the intentional introduction of a GMO into a human being, unless the GMO:
- (i) is a human somatic cell; and
 - (ii) cannot secrete or produce infectious agents as a result of the genetic modification; and
 - (iii) if it was generated using viral vectors:
 - (A) has been tested for the presence of viruses likely to recombine with the genetically modified nucleic acid in the somatic cells; and
 - (B) the testing did not detect a virus mentioned in sub-subparagraph (A); and

- (C) the viral vector used to generate the GMO as part of a previous dealing is no longer present in the somatic cells;
- (o) a dealing involving a genetically modified pathogenic organism, if the practical treatment of any disease or abnormality caused by the organism would be impaired by the genetic modification;
- (p) a dealing involving a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 4.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See <http://www.frli.gov.au>.