

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 be undertaken only 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) of Part 2 of this Schedule) 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) of Part 2 of this Schedule) involving cloning of uncharacterised nucleic acid from a toxin-producing organism;
- (d) unless the viral vector is part of a host/vector system mentioned in Part 2 of Schedule 2 or in paragraph 1.1 (c) of Part 1 or 2.1 (i) of Part 2 of this Schedule — a dealing involving donor nucleic acid in a viral vector if the donor nucleic acid:
 - (i) confers an oncogenic modification; or
 - (ii) encodes:
 - (A) immunomodulatory molecules; or
 - (B) cytokines; or
 - (C) growth factors, or components of a signal transduction pathway, that, when expressed, may lead to cell proliferation;

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- (e) a dealing involving, as host or vector, a micro-organism that has been implicated in, or has a history of causing, disease in humans, animals, plants or fungi, unless:
 - (i) the host/vector system is a system mentioned in Part 2 of Schedule 2; or
 - (ii) the donor nucleic acid is characterised and is not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; or
 - (iii) the dealing is a dealing mentioned in paragraph 2.1 (g) of Part 2 of this Schedule;
 - (f) 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) of Part 2 of this Schedule; or
 - (ii) the micro-organism is a host mentioned in Part 2 of Schedule 2;
 - (g) 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 have a heightened risk of inducing an autoimmune response;
 - (h) 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 altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility in relation to any parent or donor organism;
 - (i) a dealing involving a lentiviral vector unless:
 - (i) all structural and accessory genes have been removed from the vector to render it incapable of replication or assembly into a virion without these functions being supplied *in trans*; and
 - (ii) the vector includes a deletion that results in a transcriptionally inactive vector which, even when packaging functions are supplied *in trans*, cannot be converted into full length viral RNA; and

- (iii) the packaging cell line and packaging plasmids used contain only viral genes *gag*, *pol*, *rev* and a gene encoding an envelope protein;
- (j) 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;
- (k) a dealing producing, in each vessel containing the resultant GMO culture, more than 10 litres of that culture, other than a dealing mentioned in paragraph 2.1 (f) of Part 2 of this Schedule;
- (l) a dealing that is inconsistent with a policy principle issued by the Ministerial Council;
- (m) a dealing involving the intentional introduction of a GMO into a human being;
- (n) 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.