Part 2—Notifiable low risk dealings suitable for at least physical containment level 2 or 3

Note: Because of subregulation 12(1), a dealing mentioned in this Part is not a notifiable low risk dealing if it is also a dealing of a kind mentioned in Part 3.

2.1 Kinds of dealings suitable for at least physical containment level 2

The following kinds of notifiable low risk dealings must be undertaken, unless paragraph 13(2)(c) or subregulation 13(3) applies, in facilities certified to at least physical containment level 2 and that are appropriate for the dealings:

(a) a dealing involving whole animals (including non-vertebrates) that:
  (i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and
  (ii) does not involve any of the following:
    (A) a genetically modified laboratory guinea pig;
    (B) a genetically modified laboratory mouse;
    (C) a genetically modified laboratory rabbit;
    (D) a genetically modified laboratory rat;
    (E) a genetically modified *Caenorhabditis elegans*;

(aa) a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit, a genetically modified laboratory rat or a genetically modified *Caenorhabditis elegans*, if:
  (i) the genetic modification confers an advantage on the animal; and
  (ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification;

(b) a dealing involving a genetically modified plant;

(c) a dealing involving a host/vector system not mentioned in paragraph 1.1(c) or Part 2 of Schedule 2, if neither host nor vector has been implicated in, or has a history of causing, disease in otherwise healthy:
  (i) human beings; or
  (ii) animals; or
  (iii) plants; or
  (iv) fungi;

(d) a dealing involving a host/vector system not mentioned in Part 2 of Schedule 2, if:
  (i) the host or vector 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) the genetic modification is characterised; and

(iii) the characterisation of the genetic modification shows that it is unlikely to increase the capacity of the host or vector to cause harm;

Example: A genetic modification would not comply with subparagraph (iii) 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.

(e) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid:

(i) is characterised, and the characterisation shows that it may increase the capacity of the host or vector to cause harm; or

(ii) is uncharacterised nucleic acid from an organism that 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;

(f) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 and producing more than 25 litres of GMO culture in each vessel containing the resultant culture, if:

(i) the dealing is undertaken in a facility that is certified by the Regulator as a large scale facility; and

(ii) the donor nucleic acid satisfies the conditions set out in subitem 4(2) of Part 1 of Schedule 2;

(g) a dealing involving complementation of knocked-out genes, if the complementation is unlikely to increase the capacity of the GMO to cause harm compared to the capacity of the parent organism before the genes were knocked out;

Example: A dealing would not comply with paragraph (g) if it involved complementation that, in relation to the parent organism:

(a) provides an advantage; or

(b) adds a potential host species or mode of transmission; or

(c) increases its virulence, pathogenicity or transmissibility.

(h) a dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1 to 6 of the table in Part 2 of Schedule 2, if the donor nucleic acid is derived from either:

(i) a pathogen; or

(ii) a toxin-producing organism;

(i) a dealing involving virions of a replication defective viral vector unable to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector;

(j) a dealing involving virions of a replication defective non-retroviral vector able to transduce human cells, either without a host or with a host mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acid cannot restore replication competence to the vector; and

(ii) the dealing is not a dealing mentioned in paragraph 1.1(c);

(k) a dealing involving virions of a replication defective non-retroviral vector able to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acid cannot restore replication competence to the vector; and

(ii) the donor nucleic acid does not confer an oncogenic modification or immunomodulatory effect in humans;

(l) a dealing involving virions of a replication defective retroviral vector able to transduce human cells, either without a host or with a host mentioned in Part 2 of Schedule 2, if:

(i) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions without these functions being supplied *in trans*; and

(ii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and

(iii) either:

(A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or

(B) the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these;

(m) a dealing involving virions of a replication defective retroviral vector able to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acids does not confer an oncogenic modification or immunomodulatory effect in humans; and

(ii) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions without these functions being supplied *in trans*; and

(iii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and

(iv) either:

(A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or

(B) the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these.

2.2 Kinds of dealing suitable for at least physical containment level 3

(1) A kind of dealing that:

(a) is a kind mentioned in clause 2.1; and

(b) involves a micro-organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3;

must be undertaken, unless paragraph 13(2)(c) or subregulation 13(3) applies, in facilities certified to at least physical containment level 3 and that are appropriate for the dealings.

(2) For the purposes of paragraph (1)(b), a genetically modified micro-organism is taken to satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 if the unmodified parent micro-organism satisfies those criteria.

(3) However, subclause (2) does not apply in relation to a replication defective retroviral vector that meets the criteria in paragraph 2.1(l) or (m).