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TYPES OF DEALINGS WITH GMOs CLASSIFIED AS NOTIFIABLE LOW RISK DEALINGS (NLRDs)

Excerpt from the *Gene Technology Regulations 2001 (Statutory Rules 2001 No. 106 as amended)* (the Regulations), effective from 1 July 2007.

Part 1 of Schedule 3 of the Regulations describes the types of dealings with GMOs that are classified as NLRDs suitable for physical containment level 1. Part 2 of Schedule 3 describes the types of dealings that are classified as NLRDs suitable for physical containment level 2.

These parts also refer to the host/vector systems described in Part 2 of Schedule 2 (host/vector systems for exempt dealings). This list can be found in “What dealings with GMOs are classified as exempt dealings”.

Schedule 3 Notifiable low risk dealings in relation to a GMO

(regulations 12 and 13)

Part 1 Notifiable low risk dealings suitable for physical containment level 1

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 of this Schedule.

1.1 Kinds of dealings

The following kinds of notifiable low risk dealings may be conducted in physical containment level 1 facilities:

- (a) a dealing involving a genetically modified laboratory mouse or a genetically modified laboratory rat, unless:
 - (i) an advantage is conferred on the animal by the genetic modification; or
 - (ii) because of the genetic modification, the animal is capable of secreting or producing an infectious agent;
- (b) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid confers an oncogenic modification;
- (c) a dealing involving a defective viral vector able to transduce human cells in a host mentioned in item 4 of Part 2 of Schedule 2 (animal or human cell culture), unless:
 - (i) the vector is a retroviral vector; or
 - (ii) the donor nucleic acid confers an oncogenic modification.

Part 2 **Notifiable low risk dealings suitable for physical containment level 2**

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 of this Schedule.

2.1 **Kinds of dealings**

The following kinds of notifiable low risk dealings may be conducted in physical containment level 2 facilities:

- (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 mouse;
 - (B) a genetically modified laboratory rat;
 - (C) a genetically modified *Caenorhabditis elegans*;
- (aa) a dealing involving a genetically modified laboratory mouse or a genetically modified laboratory rat, 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;
- (ab) a dealing involving 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 (including a genetically modified flowering plant), if the dealing occurs in a facility that is designed to prevent the escape from the facility of:
 - (i) pollen, seed, spores or other propagules which may be produced in the course of the dealing; and
 - (ii) invertebrates that are capable of carrying the material mentioned in subparagraph (i);
- (ba) a dealing involving a genetically modified flowering plant, if, before flowering, all inflorescences are wholly enclosed in bags designed to prevent escape of viable pollen and seed;
- (c) a dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if:
 - (i) the host has not been implicated in, or had a history of causing, disease in human beings, animals, plants or fungi; and
 - (ii) the vector has not been implicated in, or had a history of causing, disease in human beings, animals, plants or fungi;

- (d) a dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if:
 - (i) either:
 - (A) the host has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; or
 - (B) the vector has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; and
 - (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;
- (e) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid:
 - (i) encodes a pathogenic determinant; or
 - (ii) is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi;
- (f) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 and producing more than 10 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:
 - (A) as a large scale facility; and
 - (B) to at least physical containment Level 2; and
 - (ii) the donor nucleic acid satisfies the conditions set out in item 4 of Part 1 of Schedule 2;
- (g) a dealing involving complementation of knocked-out genes, if the complementation does not alter the host range or mode of transmission, or increase the virulence, pathogenicity, or transmissibility of the host above that of the parent organism before the genes were knocked-out;
- (h) a dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of 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 the introduction of a replication defective viral vector able to transduce human cells into a host mentioned in Part 2 of Schedule 2 if:
 - (i) the donor nucleic acid is incapable of correcting a defect in the vector leading to production of replication competent virions; and
 - (ii) either:
 - (A) the vector is a retroviral vector; or
 - (B) the donor nucleic acid confers an oncogenic modification.