FIRST SCHEDULE

(regulation 2)

TECHNIQUES IN RELATION TO LIVING MODIFIED ORGANISMS TO WHICH THESE REGULATIONS ARE NOT APPLICABLE

(a) *in vitro* fertilization*;

(b) natural processes including conjugation, transduction or transformation*;

(c) cell fusion (including protoplast fusion) of prokaryotic species which can exchange genetic material through homologous recombination**;

(d) cell fusion (including protoplast fusion) of cells of any eukaryotic species within its taxonomic family, including production of hybridomas and plant cell fusions**;

(e) self-cloning, where the resulting organism is unlikely to cause disease or harm to humans, animals or plants**;

(f) mutagenesis****.

Notes:

(i) *Provided that the techniques do not involve the use of living modified organisms made by techniques other than those listed in paragraphs (c) and (e) or the use of recombinant nucleic acid molecules.

(ii) **Provided that the techniques do not involve the use of recombinant nucleic acid molecules or of living modified organisms other than those recombinant nucleic acid molecules or living modified organisms produced by one or more of the techniques under paragraphs (c) and (e).

(iii) ***Applicable for both items (i) and (ii).

(iv) "Self-cloning" –

(A) means the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), whether or not altered by enzymic or mechanical processes, into cells of the same species or into cells of phylogenetically closely related species (able to hybridize naturally) which can exchange genetic material by homologous recombination; and

(B) may include the use of recombinant vectors, with an extended history of safe use in a particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors shall not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.

CONTAINED USE ACTIVITIES WHICH ARE EXEMPTED FROM NOTIFICATION

Item	*Activity*
1	An activity with genetically modified *Caenorhabditis elegans* and *Arabidopsis,* unless – *(a)* an advantage is conferred on the organism by the genetic modification; or *(b)* as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent, toxins or other products that can potentially cause adverse effects on living organisms

Item	*Activity*
2	An activity with an organism into which genetically modified somatic cells have been introduced, if – *(a)* the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and *(b)* the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.
3	An activity involving a host/vector system mentioned in the Host/Vector Systems Not Regulated For Contained Use where the donor nucleic acid – *(a)* must be characterized and not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; *(b)* must not code for a toxin; and *(c)* must not include a viral sequence unless the donor nucleic acid – (i) is missing at least 1 gene essential for viral multiplication that – (A) is not available in the cell into which the nucleic acid is introduced; and (B) will not become available during the activity; and

Item	*Activity*
	(ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions; and *(d)* must not confer an oncogenic modification.
4	An activity involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of the Host/Vector Systems Not Regulated For Contained Use, if the donor nucleic acid is not derived from either – *(a)* a pathogen; or *(b)* a toxin-producing organism.

HOST/VECTOR SYSTEMS NOT REGULATED FOR CONTAINED USE ACTIVITIES

Item	*Class*	*Host*	*Vector*
1	Bacteria	*Escherichia coli* K12, *E. coli* B or *E. coli* C – any derivative that does not contain – *(a)* generalized transducing phages; or *(b)* genes able to complement the conjugation defect in a	1. Non-conjugative plasmids 2. Bacteriophage – (a) lambda; (b) lambdoid; (c) Fd or F1 (eg M13). 3. Non-vector systems*

Item	*Class*	*Host*	*Vector*
		non-conjugative plasmid	
		Bacillus – specified species – asporogenic strains with a reversion frequency of less than 10^{-7} – *(a) B. amyloliquefaciens;* *(b) B. licheniformis;* *(c) B. punilus;* *(d) B. subtilis;* *(e) B. thuringiensis.*	1. Non-conjugative plasmids 2. Plasmids and phages whose host range does not include *B. cereus, B. anthracts* or any other pathogenic strain of *Bacillus* 3. Non-vector systems*
		Pseudomonas putida – strain KT 2440	
		Pseudomonas putida – strain KT 2440	1. Non-conjugative plasmids including certified plasmids; pKT 262, pKT 263, pKT 264 2. Non-vector systems*
		Streptomyces – specified species – *(a) S. aureofaciens;* *(b) S. coelicolor;*	1. Non-conjugative plasmids 2. Certified plasmids: SCP2, SLP1, SLP2,

Item	*Class*	*Host*	*Vector*
		(c) S. cyaneus; *(d) S. griseus;* *(e) S. lividans;* *(f) S. parvulus;* *(g) S. rimosus;* *(h) S. venezuelae.*	PIJ101 and derivatives 3. Actinophage phi C31 and derivatives 4. Non-vector systems*
		Agrobacterium radiobacter *Agrobacterium rhizogenes* – disarmed strains *Agrobacterium tumefaciens* – disarmed strains	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2. Non-vector systems*
		Lactobacillus *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicate* *Rhizobium* (including the genus *Allorhizobium*)	1. Non-conjugative plasmids 2. Non-vector systems*
2	Fungi	*Neurospora crassa* – laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Trichoderma reesei*	1. All vectors 2. Non-vector systems*

Item	*Class*	*Host*	*Vector*
3	Slime moulds	*Dictyostelium* species	1. *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2. Non-vector systems*
4	Tissue culture	Animal or human cell cultures (including packaging cell lines)	1. Non-conjugative plasmids 2. Non-viral vectors, or defective viral vectors unable to transducer human cells 3. Avipox vectors (attenuated vaccine strains) 4. Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedron minus 5. Non-vector systems*
		Plant cell cultures	1. Non-tumorigenic disarmed Ti

Item	*Class*	*Host*	*Vector*
			plasmid vectors, or Ri plasmid vectors in *Agrobacterium tumefaciens, Agrobacterium radiobacter* or *Agrobacterium rhizogenes* 2. Non-pathogenic viral vectors 3. Non-vector systems*

Note:

1. *In relation to non-vector systems , the approved hosts may also be used in experiments where DNA is inserted into the host cell without the use of a biological vector (non-vector system) (for example, by mechanical, electrical or other means), provided that the DNA –

(a) is not derived from microorganisms able to cause disease in humans, animals or plants, unless the DNA to be introduced is fully characterised and will not increase the virulence of the host or vector;

(b) does not code for a toxin for vertebrates and is not an oncogene;

(c) must not include a viral sequence unless the donor nucleic acid –

(i) is missing at least 1 gene essential for viral multiplication that -

(A) is not available in the cell into which the nucleic acid is introduced; and

(B) will not become available during the activity; and

(ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent.

2. The exemption list for Notification includes any commercially available Host-Vector System fulfilling the criteria as specified under item 1.