SCHEDULE 8 Regulations 2(2) and 19(1)

PART 1

General

1. In this Schedule—

"GMMs" means genetically modified micro-organisms;

"HEPA" means High Efficiency Particulate Air;

"inactivation" means the complete or partial destruction of GMMs so as to ensure that any contact between the GMMs and humans or the environment is limited to an extent commensurate with the risks identified in the risk assessment and to provide a high level of protection for humans and the environment;

"plant growth facilities" means a structure, whether permanent or impermanent, designed and used principally for growing plants in a controlled and protected environment.

2. For the purposes of this Schedule where in the final column of Table 1b or 1c, a measure is specified as—

(a) a modification, it is to be read in substitution for the relevant measure in Table 1a;

(b) additional, it is to be read as an addition to the measures in Table 1a, and any measure which has been substituted for a measure in Table 1a, in accordance with paragraph 2(a).

3. For the purposes of this Schedule—

(a) Table 1a describes containment measures applicable to contained use involving micro-organisms in laboratories;

(b) Table 1a, read with Table 1b, describes containment measures applicable to contained use involving micro-organisms in plant growth facilities;

(c) Table 1a, read with Table 1c, describes containment measures applicable to contained use involving micro-organisms in animal units;

(d) Table 2 describes containment measures applicable to contained use involving micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c.

PART 2

Containment measures

Table 1a

Containment measures applicable to contained use involving micro-organisms in laboratories

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
Facilities					
1	Laboratory suite: isolation[(1)]	not required	not required	required	required
2	Laboratory: sealable for fumigation	not required	not required	required	required
Equipment					
3	Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for any bench	required for any bench	required for any bench and floor	required for any bench, floor, ceiling and walls
4	Entry to laboratory via airlock[(2)]	not required	not required	required where and to extent the risk assessment shows it is required	required
5	Negative pressure relative to the pressure of the immediate surroundings	not required	not required	required except for activities where transmission does not occur by the airborne route	required
6	Extract and input air from the laboratory must be HEPA filtered	not required	not required	HEPA filters required for extract air except for	HEPA filters required for input and extract air[(3)]

(1) "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.

(2) Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

(3) Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.

(4) Where the autoclave is outside the laboratory in which the contained use is being undertaken, but within the laboratory suite, there must be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
				activities where transmission does not occur by the airborne route	
7	Microbiological safety cabinet/enclosure	not required	required where and to extent the risk assessment shows it is required	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure
8	Autoclave	required on site	required in the building	required in the laboratory suite(4)	double ended autoclave required in laboratory
System of work					
9	Access restricted to authorised personnel only	not required	required	required	required (via airlock key procedure)
10	Biohazard sign on door	not required	required	required	required
11	Specific measures to control aerosol dissemination	not required	required so as to minimise	required so as to prevent	required so as to prevent
12	Shower	not required	not required	required where and to extent the risk assessment shows it is required	required
13	Protective clothing	suitable protective	suitable protective	suitable protective clothing	complete change of clothing and

(1) "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.

(2) Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

(3) Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.

(4) Where the autoclave is outside the laboratory in which the contained use is being undertaken, but within the laboratory suite, there must be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
		clothing required	clothing required	required; footwear required where and to extent the risk assessment shows it is required	footwear required before entry and exit
14	Gloves	not required	required where and to extent the risk assessment shows they are required	required	required
15	Efficient control of disease vectors (e.g. rodents and insects) which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required	required	required
Waste					
16	Inactivation of GMMs in effluent from hand-washing sinks and showers and similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
17	Inactivation of GMMs in contaminated material and waste	required by validated means where and to extent the risk assessment shows it is required	required by validated means	required by validated means, with waste inactivated within the laboratory suite	required by validated means, with waste inactivated within the laboratory
Other measures					
18	Laboratory to contain its own equipment	not required	not required	required, so far as is	required

(1) "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.

(2) Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

(3) Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.

(4) Where the autoclave is outside the laboratory in which the contained use is being undertaken, but within the laboratory suite, there must be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
				reasonably practicable	
19	An observation window or alternative is to be present so that occupants can be seen	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
20	Safe storage of GMMs	required where and to extent the risk assessment shows it is required	required	required	secure storage required
21	Written records of staff training	not required	required where and to extent the risk assessment shows it is required	required	required

(1) "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.

(2) Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

(3) Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.

(4) Where the autoclave is outside the laboratory in which the contained use is being undertaken, but within the laboratory suite, there must be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

Table 1b

Containment measures applicable to contained use involving micro-organisms in plant growth facilities (to be read with Table 1a as indicated in paragraph 3(b) of Part 1)

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
Facilities						
1	Permanent structure[(1)]	required where and to extent the risk assessment shows it is required	required	required	required	modification
Equipment						

(1) A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure must also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
2	Entry via a separate room with two interlocking doors	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required (via airlock key procedure)	additional
3	Control of contaminated run-off water	required where and to extent the risk assessment shows it is required	required so as to minimise run-off	required so as to prevent run-off	required so as to prevent run-off	additional
System of work						
4	Effective control of disease vectors such as insects, rodents and arthropods which could disseminate GMMs	required	required	required	required	additional
5	Effective control of pollen, seeds and other plant material which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	additional
6	Procedures for transfer of living material between the plant growth facilities, protective structure and laboratory must control dissemination of GMMs	required so as to minimise dissemination	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	additional

(1) A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure must also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

Table 1c

Containment measures applicable to contained use involving micro-organisms in animal units (to be read with Table 1a as indicated in paragraph 3(c))

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
Facilities						
1	Isolation of animal unit[(1)]	required where and to extent the risk assessment shows it is required	required	required	required	modification
2	Animal facilities[(2)] separated by lockable doors	required where and to extent the risk assessment shows it is required	required	required	required	additional
3	Animal facilities (cages, etc.) designed to facilitate decontamination (waterproof and easily washable material)	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required	required	additional
4	Floor, walls and ceiling easily washable	required where and to extent the risk assessment shows it is required	required for floor	required for floor and walls	required for floor, walls and ceiling	modification
5	Appropriate filters on isolators or isolated rooms[(3)]	not required	required where and to extent the risk assessment	required	required	additional

(1) "animal unit" means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.

(2) "animal facility" means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.

(3) "isolators" means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
			shows it is required			
6	Appropriate barriers at the room exit, and at drains or ventilation duct work	required	required	required	required	additional
7	Animals kept in appropriate containment facilities, such as cages, pens or tanks but not isolators	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	additional
8	Animals kept in isolators	not required	required where and to extent the risk assessment shows it is required	required	required	modification

(1) "animal unit" means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.

(2) "animal facility" means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.

(3) "isolators" means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table 2

Containment measures applicable to contained use involving micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c

	Containment Measure	*Containment Levels*			
		1	*2*	*3*	*4*
General					
1	Viable micro-organisms must be contained in a system which separates the process from the workplace and wider environment (closed system)	required where and to extent the risk assessment shows it is required	required	required	required
2	Closed systems located within a controlled area	not required	required where and to extent the risk	required	required

	Containment Measure	*Containment Levels*			
		1	*2*	*3*	*4*
			assessment shows it is required		
3	Control of exhaust gases from the closed system	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
4	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	required where and to extent the risk assessment shows it is required	required so as to minimise release	required so as to prevent release	required so as to prevent release
5	Inactivation of bulk culture fluids before removal from the closed system	required where and to extent the risk assessment shows it is required	required by validated means	required by validated means	required by validated means
6	Seals must be designed so as to minimise or prevent release	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
7	The controlled area designed to contain spillage of the entire contents of the closed system	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required	required
8	The controlled area sealable to permit fumigation	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
9	Biohazard signs posted	not required	required	required	required
Equipment					
10	Entry via airlock	not required	not required	required where and to extent the risk assessment shows it is required	required
11	Surfaces resistant to water, acids, alkalis, solvents, disinfectants	required for any bench	required for any bench	required for any bench and floor	required for any bench, floor, ceilings and walls

	Containment Measure	*Containment Levels*			
		1	*2*	*3*	*4*
	and decontamination agents and easy to clean				
12	Specific measures to ventilate adequately the controlled areas in order to minimise air contamination	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required
13	The controlled area maintained at an air pressure negative to the immediate surroundings	not required	not required	required where and to extent the risk assessment shows it is required	required
14	Extract and input air from the controlled area must be HEPA filtered	not required	not required	required for extract air; required where and to extent the risk assessment shows it is required for input air	required for input and extract air
System of work					
15	Access restricted to authorised personnel only	not required	required	required	required
16	Personnel must shower before leaving the controlled area	not required	not required	required where and to extent the risk assessment shows it is required	required
17	Personnel must wear protective clothing	work clothing required	work clothing required	required	complete change required before exit and entry
18	Written procedures and records of staff training	not required	required where and to extent the risk assessment shows they are required	required	required
Waste					

	Containment Measure	*Containment Levels*			
		1	*2*	*3*	*4*
19	Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
20	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	required by validated means where and to extent the risk assessment shows it to be required	required by validated means	required by validated means	required by validated means