SCHEDULE 8 Regulations 2(3) and 18(1)

Containment measures

Part I

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; and

"risk assessment" means the assessment carried out in accordance with regulation 6.

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

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

(b) additional, it shall be read as an addition to the measures in Table 1a, subject to the substitution, where appropriate, of an individual measure in Table 1a by a measure specified as a modification in the Table in question.

3. For the purposes of this Schedule—

(a) Table 1a describes containment measures applicable to activities involving genetic modification of micro-organisms in laboratories;

(b) Table 1a, read with Table 1b, describes containment measures applicable to activities involving genetic modification of micro-organisms in plant growth facilities;

(c) Table 1a, read with Table 1c, describes containment measures applicable to activities involving genetic modification of micro-organisms in animal units;

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

Part II

Table 1a:

Containment measures for activities involving genetic modification of micro-organisms in laboratories

Containment Measures	*Containment Levels*			
	1	*2*	*3*	*4*
1. Laboratory suite: isolation (Note 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 bench	required for bench	required for bench and floor	required for bench, floor ceiling and walls
4. Entry to lab via airlock (Note 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	required where and to extent the risk assessment shows it is required	required	required
6. Extract and input air from the	not required	not required	HEPA filters required for extract air	HEPA filters required for input

NOTES

1. In the Table above, “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 activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall 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*
laboratory shall be HEPA filtered				and extract air (Note 3)
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	Class III cabinet required
8. Autoclave	required on site	required in the building	required in the laboratory suite (Note 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. Specific measures to control aerosol dissemination	not required	required so as to minimise	required so as to prevent	required so as to prevent
11. Shower	not required	not required	required where and to extent the risk assessment shows it is required	required
12. Protective clothing	suitable protective clothing required	suitable protective clothing required	suitable protective clothing required; footwear required where and to extent the risk assessment shows it is required	complete change of clothing and footwear required before entry and exit

NOTES

1. In the Table above, “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 activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall 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*
13. Gloves	not required	required where and to extent the risk assessment shows they are required	required	required
14. Efficient control of disease vectors (eg rodents and insects) which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required	required	required
15. Specified disinfection procedures in place	required where and to extent the risk assessment shows they are required	required	required	required
Waste				
16. Inactivation of GMMs in effluent from handwashing 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	required by validated means	required by validated means	required by validated means
Other measures				
18. Laboratory to contain its own equipment	not required	not required	required, so far as is reasonably practicable	required
19. An observation	required where and to extent the	required where and to extent the	required	required

NOTES

1. In the Table above, “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 activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall 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*
window or alternative is to be present so that occupants can be seen	risk assessment shows it is required	risk assessment shows it is 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 they are required	required	required

NOTES

1. In the Table above, "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 activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall 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 for activities involving genetic modification of micro-organisms in plant growth facilities (to be read with Table 1a as indicated in paragraph 3)

Containment Measures	*Containment Levels*				*Additional/ modification*
	1	*2*	*3*	*4*	
Building					
1. Permanent structure (Note 1)	required where and to extent the risk assessment shows it is required	required	required	required	Modification
Equipment					

NOTE

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 shall 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 prevent 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 shall control dissemination of GMMs	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	required so as to prevent dissemination	Additional

NOTE

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 shall 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 for activities involving genetic modification of micro-organisms in animal units (to be read with Table 1a as indicated in paragraph 3)

Containment Measures	*Containment Levels*				*Additional/ modification*
	1	*2*	*3*	*4*	
Facilities					
1. Isolation of animal unit (Note 1)	required where and to extent the risk assessment shows it is required	required	required	required	Modification
2. Animal facilities (Note 2) separatedwhere and by lockable doors	required to extent the risk assessment shows they are 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 they are required	required where and to extent the risk assesment shows they are required	required	required	Additional
4. Floor, walls and ceiling easily washable	required where and to extent the risk assessment shows they are required	required for floor	required for floor and walls	required for floor, walls and ceiling	Modification
5. Appropriate filters on isolators or isolated rooms (Note 3)	not required	required where and to extent the risk assessment	required	required	Additional

NOTES

1. In the Table above, “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. In the Table above and in Note 1 above, “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. In the Table above, “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 they are required			
6. Incinerator for disposal of animal carcasses	required to be accessible	required to be accessible	required to be accessible	required to be on site	Additional
7. Appropriate barriers at the room exit, and at drains or ventilation duct work	required	required	required	required	Additional
8. Animals kept in appropriate containment facilities, such as cages, pens, tanks or 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

NOTES
1. In the Table above, "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. In the Table above and in Note 1 above, "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. In the Table above, "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 for activities involving genetic modification of micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c

Containment Measures	*Containment Levels*			
	1	*2*	*3*	*4*
General				
1. Viable micro-organisms shall be contained in a system which separates the process from the workplace and wider	required where and to extent the risk assessment shows it is required	required	required	required

Containment Measures	*Containment Levels*			
	1	*2*	*3*	*4*
environment (closed system)				
2. Closed systems located within a controlled area	not required	required where and to extent the risk assessment shows they are required	required	required and required to be purpose built
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 shall 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 where and to extent the risk assessment shows it is required	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	required where and to extent the risk assessment	required	required	required

Containment Measures	*Containment Levels*			
	1	*2*	*3*	*4*
	shows it is 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 and decontamination agents and easy to clean	required for any bench	required for any bench	required for floor and any bench	required for bench, floor, ceiling and walls
12. Specific measures to adequately ventilate 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 shall be HEPA filtered	not required	not required	required for extract air, optional 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. Decontamination and washing facilities provided for personnel	required	required	required	required

Containment Measures	*Containment Levels*			
	1	*2*	*3*	*4*
17. Personnel shall shower before leaving the controlled area	not required	not required	required where and to extent the risk assessment shows it is required	required
18. Personnel shall wear protective clothing	work clothing required	work clothing required	required	complete change required before exit and entry
19. Written procedures and records of staff training	not required	not required	required	required
Waste				
20. Inactivation of GMMs in effluent from handwashing sinks and showers or similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
21. Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	required by validated means	required by validated means	required by validated means	required by validated means