SCHEDULE 8

CONTAINMENT MEASURES

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

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*
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 laboratory shall be HEPA filtered	not required	not required	HEPA filters required for extract air	HEPA filters required for input 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	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*
				assessment shows it is 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
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	not required	not required	required where and to	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*
	effluent from handwashing sinks and showers and similar effluents			extent the risk assessment shows it is 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 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	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					
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	required where and to extent the risk	required so as to minimise	required so as to prevent	required so as to prevent	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.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	other plant material which could disseminate GMMs	assessment shows it is required				
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	required	required	required	Modification

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 it is required				
2	Animal facilities **(Note 2)** separated by lockable doors	required where and 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 shows they are required	required	required	Additional
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	required	required	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*	
	the room exit, and at drains or ventilation duct work					
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 environment (closed system)	required where and to extent the risk assessment shows it is required	required	required	required
2	Closed systems located within	not required	required where and to extent the risk assessment	required	required and required to be purpose built

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	a controlled area		shows they are 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 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	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	required where and to extent the risk assessment shows it is required	required	required	required

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	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	required	required	required	required

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	provided for personnel				
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