SCHEDULE 1

Regulation 2(1)

Classes of contained use

Class	*Description*
1	Contained use of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
2	Contained use of low risk, for which containment level 2 is appropriate to protect human health and the environment.
3	Contained use of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
4	Contained use of high risk, for which containment level 4 is appropriate to protect human health and the environment.

SCHEDULE 2

Regulations 2(1) and 3(1)

PART 1

Techniques constituting genetic modification

1. The techniques which constitute genetic modification referred to in sub-paragraph (a) of the definition of "genetic modification" in regulation 2(1) are—

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(b) techniques involving the direct introduction into an organism of heritable genetic material prepared outside the organism, including micro-injection, macro-injection and micro-encapsulation;

(c) cell fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2

Techniques which are not considered to result in genetic modification

2. The following techniques are not considered to result in genetic modification provided that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms made by techniques other than those listed in Part 3—

(a) in vitro fertilisation;

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

(c) polyploidy induction.

PART 3

Techniques to which these Regulations do not apply

3. These Regulations (except regulation 18) do not apply to the following techniques of genetic modification, provided that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms other than those made by one or more of the following techniques—

(a) mutagenesis;

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

(c) cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions;

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

4. In paragraph 3—

(a) "self-cloning" 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 which can exchange genetic material by homologous recombination; and

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

SCHEDULE 3

Regulations 2(3), 3(4) and 5

PART 1

Matters to be taken into account in carrying out an assessment for the purposes of regulation 5

1. The following matters must be taken into account in carrying out an assessment for the purposes of regulation 5—

(a) any potentially harmful effects, in particular those associated with—

(i) the recipient micro-organism;

(ii) the inserted genetic material (originating from the donor organism);

(iii) the vector;

(iv) the donor micro-organism (where that donor micro-organism is used during the contained use);

(v) the resulting genetically modified micro-organism;

(b) the characteristics of the contained use;

(c) the severity of the potentially harmful effects;

(d) the likelihood of the potentially harmful effects being realised;

(e) the disposal of waste and effluents.

2. In paragraph 1, "potentially harmful effects" includes—

(a) disease to humans including allergenic or toxic effects;

(b) disease to animals or plants;

(c) adverse effects resulting from the inability to treat disease or offer an effective prophylaxis;

(d) adverse effects resulting from establishment or dissemination of the genetically modified micro-organisms in the environment;

(e) adverse effects resulting from the natural transfer of genetic material to or from other organisms;

(f) adverse effects resulting from the likely interaction of the genetically modified micro-organism with other organisms at the premises where the contained use is to be conducted.

PART 2

Steps to be included when carrying out an assessment for the purposes of regulation 5

3. An assessment carried out for the purposes of regulation 5 must include—

(a) identification of any harmful properties of the recipient and, where appropriate, the donor micro-organism;

(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;

(c) recognition that, in general, only contained use which shows the following characteristics is appropriate for inclusion in class 1 as described in Schedule 1—

(i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants;

(ii) the nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, animals or plants, or likely to cause deleterious effects on the environment; and

(iii) the genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to have deleterious effects on the environment;

(d) consideration of relevant EU legislation, including Directive (EC) No 2000/54 of the European Parliament and the Council on the protection of workers from risks related to exposure to biological agents at work(**1**), other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms;

(e) identification of the provisional level of risk associated with the genetically modified micro-organism;

(f) consideration of—

(i) the characteristics of the environment likely to be exposed;

(ii) the characteristics of the contained use involving micro-organisms;

(iii) any contained use of micro-organisms which cannot be controlled adequately by standard laboratory procedures, and which presents risks which require controls for each individual case;

(g) adjustment of the provisional level of risk in the light of the matters referred to in sub-paragraph (f);

(**1**) OJ No L 262, 17.10.2000, p21.

(h) selection of the appropriate containment measures from those specified in the applicable table in Schedule 8 on the basis of the provisional level of risk as adjusted in accordance with sub-paragraph (g);

(i) assignment of the contained use to the appropriate containment level, in accordance with paragraph 4;

(j) classification of the contained use in the class of the same number as that of the appropriate containment level;

(k) review and reconsideration of that classification in the light of the completed risk assessment.

4. To assign a contained use to the appropriate containment level for the purposes of paragraph 3(i), the person carrying out the risk assessment must—

(a) first identify for each selected containment measure the column in the applicable table in Schedule 8 having the lowest number in which that selected containment measure is shown as being required, regardless of whether or not such requirement is subject to any qualification;

(b) then select the highest number of all the columns identified in accordance with sub-paragraph (a); and

(c) then assign the contained use to the containment level of that highest number.

5. In paragraph 4, "selected containment measure" means an appropriate containment measure selected in accordance with paragraph 3(h).

SCHEDULE 4

Regulation 6

PART 1

Matters to be taken into account in carrying out an assessment for the purposes of regulation 6

1. The following matters must be taken into account in carrying out an assessment for the purposes of regulation 6—

(a) any potentially harmful effects, in particular those associated with—

(i) the recipient organism;

(ii) the inserted genetic material (originating from the donor organism);

(iii) the vector;

(iv) the donor organism;

(v) the resulting genetically modified organism;

(b) the characteristics of the contained use;

(c) the severity of the potentially harmful effects;

(d) the likelihood of the potentially harmful effects being realised.

2. In paragraph 1, "potentially harmful effects" includes—

(a) disease to humans including allergenic or toxic effects;

(b) acting as a human disease vector or reservoir;

(c) adverse effects to humans arising from change in behaviour or in physical nature;

(d) adverse effects arising from the inability to treat human disease or offer effective prophylaxis.

PART 2

Steps to be included when carrying out an assessment for the purposes of regulation 6

3. An assessment carried out for the purposes of regulation 6 must include—

(a) identification of any harmful properties of the recipient and, where appropriate, the donor organism;

(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;

(c) identification of the provisional level of risk associated with the genetically modified organisms;

(d) selection of containment and other protective measures on the basis of—

(i) the provisional level of risk; and

(ii) the characteristics of the contained use;

(e) adjustment of the level of risk in the light of the matters referred to in sub-paragraph (d);

(f) review and reconsideration of the containment and other protective measures in the light of the steps required by sub-paragraphs (a) to (e).

SCHEDULE 5

Regulations 9(2), 14(1)and 28(3)

Information required for a notification under regulation 9(2)

A notification required for the purposes of regulation 9(2) must contain the following information—

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;

(b) the name of the person with specific responsibility for the supervision and safety of contained use;

(c) information on the training and qualifications of that person;

(d) details of the arrangements for obtaining advice on risk assessments in accordance with regulation 8, including details of any genetic modification safety committee if established;

(e) the address of the premises where the contained use is to be carried out and a general description of the premises, together with, if required by regulation 9(6), the principal address of the premises;

(f) the nature of the work to be undertaken;

(g) the class of any contained use involving micro-organisms;

(h) where the first contained use to be carried out in those premises is a class 1 contained use—

(i) a summary of the risk assessment of that contained use;

(ii) any advice received in relation to the risk assessment from a person or genetic modification safety committee in accordance with regulation 8;

(iii) information on waste management;

(iv) confirmation that the emergency services, and any body or authority liable to be affected by an accident to which any emergency plan relates, will be informed of the contents of the emergency plan and of any relevant revisions;

(i) where the first contained use to be carried out in those premises is a contained use involving larger GMOs and that contained use is not notifiable under regulation 12(2)—

(i) a copy of the risk assessment; and

(ii) confirmation that the emergency services, and any body or authority liable to be affected by an accident to which any emergency plan relates, will be informed of the contents of the emergency plan and of any relevant revisions.

SCHEDULE 6

Regulations 10(2), 11(2), 12(2),14(1), 28(3) and 33(6)

Information required for a notification under regulation 10(2), 11(2) or 12(2)

A notification required for the purposes of regulation 10(2), 11(2) or 12(2) must contain the following information except where it is required only for a specified regulation—

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;

(b) any centre number allocated by the competent authority in respect of the premises at which the contained use is to be undertaken and the date of the notification required by regulation 9(2) relating to those premises;

(c) the name of the person with specific responsibility for supervision and safety of contained use;

(d) information on the training and qualifications of that person;

(e) the recipient or parental micro-organism to be used;

(f) the donor micro-organism to be used;

(g) where applicable, the host-vector system to be used;

(h) the source and intended function of the genetic material involved in the modification;

(i) the identity and characteristics of the genetically modified organism;

(j) the purpose of the contained use, including its expected results;

(k) for regulation 10(2) the approximate culture volumes to be used;

(l) for regulation 11(2) the culture volumes to be used;

(m) a description of the containment and other protective measures to be applied, including—

(i) information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination; and

(ii) for regulation 10(2) justification for not applying any containment measure at containment level 2;

(iii) for regulation 11(2), for class 3 contained use, justification for not applying any containment measure at containment level 3;

(iv) for regulation 11(2), for class 4 contained use, justification for not applying any containment measure at containment level 4;

(n) for regulations 10(2) and 11(2) a copy of the risk assessment;

(o) for regulations 10(2) and 11(2) the advice received in relation to that assessment from a genetic modification safety committee;

(p) for regulation 12(2) a copy of the risk assessment;

(q) information in relation to any accident prevention and emergency plans including—

(i) the information necessary for the competent authority to evaluate any emergency plan;

(ii) confirmation that the emergency services, and any body or authority liable to be affected by an accident to which any emergency plan relates, will be informed of the contents of the emergency plan and of any relevant revisions;

(iii) for regulation 11(2), in addition—

(aa) any specific hazards arising from the location of the installation;

(bb) the preventive measures applied, including safety equipment, alarm systems and containment methods;

(cc) procedures and plans for verifying the continuing effectiveness of the containment measures;

(dd) a description of the information provided to workers;

(r) for regulation 11(2) a description of the parts of the installation;

(s) for regulation 11(2) whether the genetically modified organism is likely to be subject to transboundary movement.

SCHEDULE 7

Regulation 18

General principles of good microbiological practice and of good occupational safety and hygiene

The general principles of good microbiological practice and of good occupational safety and hygiene are as follows—

(a) keeping workplace and environmental exposure to any genetically modified micro-organism to the lowest reasonably practicable level;

(b) exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary;

(c) testing adequately and maintaining control measures and equipment;

(d) testing, where necessary, for the presence of viable process organisms outside the primary physical containment;

(e) providing appropriate training of personnel;

(f) establishing a genetic modification safety committee, if required;

(g) formulating and implementing local codes of practice for the safety of personnel, as required;

(h) displaying biohazard signs where appropriate;

(i) providing washing and decontamination facilities for personnel;

(j) keeping adequate records;

(k) prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption;

(l) prohibiting mouth pipetting;

(m) providing written standard operating procedures where appropriate to ensure safety;

(n) having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms;

(o) providing safe storage for contaminated laboratory equipment and materials where appropriate.

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