

ANNEX IV

CONTAINMENT AND OTHER PROTECTIVE MEASURES **General principles**

1. These tables present the normal minimum requirements and measures necessary for each level of containment.

Containment is also achieved through the use of good work practices, training, containment equipment and special installation design. For all activities involving GMMs the principles of good microbiological practice and the following principles of good occupational safety and hygiene shall apply:

- (i) to keep workplace and environmental exposure to any GMM to the lowest practicable level;
- (ii) to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary;
- (iii) to test adequately and maintain control measures and equipment;
- (iv) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;
- (v) to provide appropriate training of personnel;
- (vi) to establish biological safety committees or subcommittees, if required;
- (vii) to formulate and implement local codes of practice for the safety of personnel, as required;
- (viii) where appropriate, to display biohazard signs;
- (ix) to provide washing and decontamination facilities for personnel;
- (x) to keep adequate records;
- (xi) to prohibit eating, drinking, smoking, applying cosmetics or the storing of food for human consumption in the work area;
- (xii) to prohibit mouth pipetting;
- (xiii) to provide written standard operating procedures where appropriate to ensure safety;
- (xiv) to have effective disinfectants and specified disinfection procedures available in case of spillage of GMMs;
- (xv) to provide safe storage for contaminated laboratory equipment and materials, when appropriate.

2. The titles of the tables are indicative:

Table I A presents minimum requirements for laboratory activities.

Table I B presents additions to and modifications of Table I A for glasshouse/growth-room activities involving GMMs.

Table I C presents additions to and modifications of Table I A for activities with animals involving GMMs.

Table II presents minimum requirements for activities other than laboratory activities.

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In some particular cases, it might be necessary to apply a combination of measures, from Table I A and Table II, of the same level.

In some cases users may, with the agreement of the competent authority, not apply a specification under a particular containment level or combine specifications from two different levels.

In these tables 'optional' means that the user may apply these measures on a case-by-case basis, subject to the assessment referred to in Article 4(2).

3. In implementing this Annex, Member States may in addition incorporate in the following tables the general principles set out in points 1 and 2, with a view to clarifying the requirements.

TABLE I A

Containment and other protective measures for laboratory activities

Specifications		Containment levels			
		1	2	3	4
1	Laboratory suite: isolation ^a	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required
Equipment					
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents, and easy to clean	Required (bench)	Required (bench)	Required (bench, floor)	Required (bench, floor, ceiling, walls)
4	Entry to lab via airlock ^b	Not required	Not required	Optional	Required
5	Negative pressure	Not required	Not required	Required except for ^c	Required
a	Isolation	= the laboratory is separated from other areas in the same building or is in a separate building.			
b	Airlock	= 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.			
c	Activities where transmission does not occur via airborne route.				
d	HEPA	= High efficiency particulate air.			
e	Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.				
f	With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.				

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	relative to the pressure of the immediate environment				
6	Extract and input air from the laboratory should be HEPA ^d -filtered	Not required	Not required	Required (HEPA — extract air except for ^e)	Required (HEPA— input and extract air ^e)
7	Microbiological safety post	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite ^f	In lab = double-ended
System of work					
9	Restricted access	Not required	Required	Required	Required
10	Biohazard sign on the door	Not required	Required	Required	Required
11	Specific measures to control aerosol dissemination	Not required	Required minimise	Required prevent	Required prevent
13	Shower	Not required	Not required	Optional	Required
14	Protective clothing	Suitable protective clothing	Suitable protective clothing	Suitable protective clothing and (optional) footwear	Complete change of clothing and footwear before entry and exit
15	Gloves	Not required	Optional	Required	Required
18	Efficient vector control (e.g. for	Optional	Required	Required	Required
a	Isolation	=	the laboratory is separated from other areas in the same building or is in a separate building.		
b	Airlock	=	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.		
c	Activities where transmission does not occur via airborne route.				
d	HEPA	=	High efficiency particulate air.		
e	Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.				
f	With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.				

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	rodents and insects)				
Waste					
19	Inactivation of GMMs in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	Optional	Required
20	Inactivation of GMMs in contaminated material and waste	Optional	Required	Required	Required
Other measures					
21	Laboratory to contain its own equipment	Not required	Not required	Optional	Required
23	An observation window or alternative is to be present so that occupants can be seen	Optional	Optional	Optional	Required
a	Isolation	=	the laboratory is separated from other areas in the same building or is in a separate building.		
b	Airlock	=	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.		
c	Activities where transmission does not occur via airborne route.				
d	HEPA	=	High efficiency particulate air.		
e	Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.				
f	With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.				

TABLE I B

Containment and other protective measures for glasshouses and growth-rooms

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The terms ‘glasshouse’ and ‘growth-room’ refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment. All provisions of Table I A shall apply with the following additions/modifications:

Specifications		Containment levels			
		1	2	3	4
Building					
1	Glasshouse: permanent structure ^a	Not required	Required	Required	Required
Equipment					
3	Entry via a separate room with two interlocking doors	Not required	Optional	Optional	Required
4	Control of contaminated run-off water	Optional	Minimise ^b run-off	Prevent run-off	Prevent run-off
System of work					
6	Measures to control undesired species such as insects, rodents, arthropods	Required	Required	Required	Required
7	Procedures for transfer of living material between the glasshouse/ growth-room, protective structure and laboratory shall control dissemination of GMMs	Minimise dissemination	Minimise dissemination	Prevent dissemination	Prevent dissemination
<p>a The glasshouse shall consist of a permanent structure with a continuous waterproof covering, located on a site graded to prevent entry of surface-water run-off, and with self-closing lockable doors.</p> <p>b Where transmission can occur through the ground.</p>					

TABLE I C

Containment and other protective measures for activities in animal units

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All provisions of Table I A shall apply with the following additions/modifications:

Specifications		Containment levels			
		1	2	3	4
Facilities					
1	Isolation of animal unit ^a	Optional	Required	Required	Required
2	Animal facilities ^b separated by lockable doors	Optional	Required	Required	Required
3	Animal facilities designed to facilitate decontamination (waterproof and easily washable material (cages, etc.))	Optional	Optional	Required	Required
4	Floor and/or walls easily washable	Optional	Required (floor)	Required (floor and walls)	Required (floor and walls)
5	Animals kept in appropriate containment facilities such as cages, pens or tanks	Optional	Optional	Optional	Optional
6	Filters on isolators or isolated room ^c	Not required	Optional	Required	Required
a	Animal unit	:	a building or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves, food storage areas, etc.		
b	Animal facility	:	a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures.		
c	Isolators	:	transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.		

TABLE II

Containment and other protective measures for other activities

Specifications		Containment levels			
		1	2	3	4

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General					
1	Viable micro-organisms should be contained in a system which separates the process from the environment (closed system)	Optional	Required	Required	Required
2	Control of exhaust gases from the closed system	Not required	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
4	Inactivation of bulk culture fluids before removal from the closed system	Optional	Required, by validated means	Required, by validated means	Required, by validated means
5	Seals should be designed so as to minimise or prevent release	No specific requirement	Minimise dissemination	Prevent dissemination	Prevent dissemination
6	The controlled area should be designed to contain spillage of the entire contents of	Optional	Optional	Required	Required

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	the closed system				
7	The controlled area should be sealable to permit fumigation	Not required	Optional	Optional	Required
Equipment					
8	Entry via airlock	Not required	Not required	Optional	Required
9	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents, and easy to clean	Required (bench if any)	Required (bench if any)	Required (bench if any, floor)	Required (bench, floor, ceiling, walls)
10	Specific measures to adequately ventilate the controlled area in order to minimise air contamination	Optional	Optional	Optional	Required
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Optional	Required
12	Extract and input air from the controlled area should be HEPA filtered	Not required	Not required	Required (extract air, optional for input air)	Required (input and extract air)
System of work					
13	Closed systems should be	Not required	Optional	Required	Required

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	located within a controlled area				
14	Access should be restricted to nominated personnel only	Not required	Required	Required	Required
15	Biohazard signs should be posted	Not required	Required	Required	Required
17	Personnel should shower before leaving the controlled area	Not required	Not required	Optional	Required
18	Personnel should wear protective clothing	Required (work clothing)	Required (work clothing)	Required	Complete change before exit and entry
Waste					
22	Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents	Not required	Not required	Optional	Required
23	Inactivation of GMMs in contaminated material and waste, including those in process effluent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means