

SCHEDULE 3

SPECIAL PROVISIONS RELATING TO BIOLOGICAL AGENTS

PART III

CONTAINMENT MEASURES FOR INDUSTRIAL PROCESSES

<i>Containment measures</i>	<i>Containment levels</i>		
	<i>2</i>	<i>3</i>	<i>4</i>
1. Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system).	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to—	Minimise release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to—	Minimise release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been—	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to—	Minimise release	Prevent release	Prevent release
6. Closed systems should be located within a controlled area—	Optional	Optional	Yes, and purpose-built
(a) (a) hazard signs should be posted;	Optional	Yes	Yes
(b) (b) access should be	Optional	Yes	Yes, via air-lock

Status: This is the original version (as it was originally made).

Containment measures	Containment levels		
	2	3	4
restricted to nominated personnel only;			
(c) (b) personnel should wear protective clothing;	Yes, work clothing	Yes	Yes, a complete change
(d) (c) decontamination and washing facilities should be provided for personnel;	Yes	Yes	Yes
(e) (d) personnel should shower before leaving the controlled area;	No	Optional	Yes
(f) (f) effluent from sinks and showers should be collected and inactivated before release;	No	Optional	Yes
(g) (g) the controlled area should be adequately ventilated to minimise air contamination;	Optional	Optional	Yes
(h) (h) the controlled area should be maintained at an air pressure negative to atmosphere;	No	Optional	Yes

Containment measures	Containment levels		
	2	3	4
(i) (i) input and extract air to the controlled area should be HEPA filtered;	No	Optional	Yes
(j) (j) the controlled area should be designed to contain spillage of the entire contents of closed system;	Optional	Yes	Yes
(k) (k) controlled area should be sealable to permit fumigation.	No	Optional	Yes
7. Effluent treatment before final discharge.	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated physical means