

SCHEDULE 3

ADDITIONAL PROVISIONS RELATING TO WORK WITH BIOLOGICAL AGENTS

PART III

CONTAINMENT MEASURES FOR INDUSTRIAL PROCESSES

<i>Containment measures</i>	<i>Containment levels</i>		
	2	3	4
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.

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	2	3	4
restricted to nominated personnel only;			
(c) <del>(b)</del> personnel should wear protective clothing;	Yes, work clothing.	Yes.	Yes, a complete change.
<del>(d)</del> (d) decontamination and washing facilities should be provided for personnel;	Yes.	Yes.	Yes.
(e) <del>(c)</del> 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.

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	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) the 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.