SCHEDULE 9 Regulation 7(10)

SPECIAL PROVISIONS RELATING TO BIOLOGICAL AGENTS

PART I

PROVISIONS OF GENERAL APPLICATION TO BIOLOGICAL AGENTS

Interpretation

1. In this Schedule—

"cell culture" means the *in-vitro* growth of cells derived from multicellular organisms;

"diagnostic service" means any activity undertaken solely with the intention of—

(a) testing for the presence of or identifying a biological agent,

(b) isolating or identifying other organisms from specimens or samples containing or suspected of containing a biological agent,

(c) analysing specimens or samples from a human patient or animal in which a biological agent is or is suspected of being present for purposes relating to the assessment of the clinical progress, or assistance in the clinical management, of that patient or animal,

and "diagnosis" shall be construed accordingly;

"Group" means one of the four hazard Groups specified in paragraph 3 to which biological agents are assigned.

Application

2.—(1) This Schedule shall have effect with a view to protecting employees against risks to their health, whether immediate or delayed, arising from exposure to biological agents except that paragraph 11 shall not apply in relation to a particular biological agent where the results of the assessment made under regulation 6 indicate that—

(a) the activity does not involve a deliberate intention to work with or use that biological agent; and

(b) there is no significant risk to the health of employees associated with that biological agent.

(2) Unless otherwise expressly provided, the provisions of this Schedule shall have effect in addition to and not in substitution for other provisions of these Regulations.

Classification of biological agents

3.—(1) The Health and Safety Commission shall approve and publish for the purposes of this Schedule a document, which may be revised or re-issued from time to time, entitled "Categorisation of Biological Agents according to hazard and categories of containment" containing a list of biological agents together with the classification of each agent which it has approved, and any reference in this Schedule to "approved classification" in relation to a particular biological agent shall be construed as a reference to the classification of that agent which appears in the said document.

(2) Where a biological agent has an approved classification any reference in these Regulations to a particular Group in relation to that agent shall be taken as a reference to the Group to which that agent has been assigned in that approved classification.

(3) Where a biological agent does not have an approved classification, the employer shall provisionally classify that agent in accordance with sub-paragraph (4) below, having regard to the nature of the agent and the properties of which he may reasonably be expected to be aware.

(4) When provisionally classifying a biological agent the employer shall assign that agent to one of the following Groups according to its level of risk of infection and, if in doubt as to which of two alternative Groups is the most appropriate, he shall assign it to the higher of the two—

(a) Group 1 — unlikely to cause human disease;

(b) Group 2 — can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available;

(c) Group 3 — can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available;

(d) Group 4 — causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

Assessment of health risks

4. Without prejudice to the generality of regulation 6, every employer who intends to carry on any work which is liable to expose his employees to any biological agent shall take account of the Group into which that agent is classified when making an assessment of the risks created by that work.

Prevention of exposure to a biological agent

5. Without prejudice to the generality of regulation 7(1), if the nature of the activity so permits, every employer shall ensure that the exposure of his employees to a particular biological agent is prevented by substituting a biological agent which is less hazardous.

Control of exposure to biological agents

6.—(1) Where there is a risk of exposure to a biological agent and it is not otherwise reasonably practicable to prevent that exposure then it shall be adequately controlled, in particular by the following measures which are to be applied in the light of the results of the assessment—

(a) keeping as low as practicable the number of employees exposed or likely to be exposed to the biological agent;

(b) designing work processes and engineering control measures so as to prevent or minimise the release of biological agents into the place of work;

(c) displaying the biohazard sign shown in Part IV of this Schedule and other relevant warning signs;

(d) drawing up plans to deal with accidents involving biological agents;

(e) specifying appropriate decontamination and disinfection procedures;

(f) instituting means for the safe collection, storage and disposal of contaminated waste, including the use of secure and identifiable containers, after suitable treatment where appropriate;

(g) making arrangements for the safe handling and transport of biological agents, or materials that may contain such agents, within the workplace;

(h) specifying procedures for taking, handling and processing samples that may contain biological agents;

(i) providing collective protection measures and, where exposure cannot be adequately controlled by other means, individual protection measures including, in particular, the supply of appropriate protective clothing or other special clothing;

(j) where appropriate, making available effective vaccines for those employees who are not already immune to the biological agent to which they are exposed or are liable to be exposed;

(k) instituting hygiene measures compatible with the aim of preventing or reducing the accidental transfer or release of a biological agent from the workplace, including, in particular—

(i) the provision of appropriate and adequate washing and toilet facilities, and

(ii) the prohibition of eating, drinking, smoking and application of cosmetics in working areas where there is a risk of contamination by biological agents.

(2) In this paragraph, "appropriate" in relation to clothing and hygiene measures means appropriate for the risks involved and the conditions at the place where exposure to the risk may occur.

Special control measures for health and veterinary care facilities

7. In health and veterinary care isolation facilities where there are human patients or animals which are, or are suspected of being, infected with a Group 3 or Group 4 biological agent, the employer shall select the most suitable containment measures from those listed in Part II of this Schedule with a view to controlling adequately the risk of infection.

Special control measures for laboratories, animal rooms and industrial processes

8.—(1) Every employer who is engaged in any of the activities specified in sub-paragraph (3) below shall ensure that measures taken to control adequately the exposure of his employees to biological agents include, in particular, the most suitable combination of containment measures from those listed in Parts II and III of this Schedule as appropriate, taking into account—

(a) the nature of the activity specified in sub-paragraph (3) below;

(b) the minimum containment level specified in sub-paragraph (4) below;

(c) the assessment of risk made under regulation 6; and

(d) the nature of the biological agent concerned.

(a) (2) (a) An employer who is engaged in any of the activities specified in sub-paragraphs (a) or (b) of paragraph (3) below shall select measures from Part II of this Schedule;

(b) an employer who is engaged in the activity specified in sub-paragraph (c) of paragraph (3) below shall select measures from Part III of this Schedule and, subject to paragraph (4) below, when making that selection he may combine measures from different categories of containment on the basis of a risk assessment related to any particular process or part of a process.

(3) The activities referred to in sub-paragraph (1) above are—

(a) research, development, teaching or diagnostic work in laboratories which involves the handling of a Group 2, Group 3 or Group 4 biological agent or material containing such an agent;

(b) keeping or handling of laboratory animals which have been deliberately infected with a Group 2, Group 3 or Group 4 biological agent or which are, or are suspected of being, naturally infected with such an agent; and

(c) industrial processes which involve the use of a Group 2, Group 3 or Group 4 biological agent.

(4) The minimum containment level referred to in sub-paragraph (1) above shall be—

(a) level 2 for activities involving the handling of a Group 2 biological agent;

(b) level 3 for activities involving the handling of a Group 3 biological agent;

(c) level 4 for activities involving the handling of a Group 4 biological agent;

(d) level 2 for laboratories which do not intentionally work with biological agents but handle materials in respect of which there exist uncertainties about the presence of a Group 2, Group 3 or Group 4 biological agent;

(e) level 3 or 4, where appropriate, for laboratories which do not intentionally work with biological agents but where the employer knows or suspects that such a containment level is necessary; except where guidelines approved by the Health and Safety Commission indicate that, in the particular case, a lower containment level is appropriate; and

(f) level 3 for activities where it has not been possible to carry out a conclusive assessment but concerning which it appears that the activity might involve a serious health risk for employees.

Examination and maintenance of personal protective equipment

9.—(1) Every employer who provides personal protective equipment, including protective clothing, to meet the requirements of these Regulations as they apply to biological agents shall ensure that it is—

(a) properly stored in a well-defined place;

(b) checked and cleaned at suitable intervals; and

(c) when discovered to be defective, repaired or replaced before further use.

(2) Personal protective equipment which may be contaminated by biological agents shall be—

(a) removed on leaving the working area; and

(b) kept apart from uncontaminated clothing and equipment.

(3) The employer shall ensure that the equipment referred to in sub-paragraph (2) above is subsequently decontaminated and cleaned or, if necessary, destroyed.

Information for employees

10.—(1) Every employer shall provide written instructions at the workplace and, if appropriate, display notices which shall include the procedure to be followed in the case of—

(a) an accident or incident which has or may have resulted in the release of a biological agent which could cause severe human disease;

(b) the handling of a Group 4 biological agent or material that may contain such an agent.

(2) Every employee shall report forthwith, to his employer or to any other employee of that employer with specific responsibility for the health and safety of his fellow employees, any accident or incident which has or may have resulted in the release of a biological agent which could cause severe human disease.

(3) Every employer shall inform his employees or their representatives—

(a) forthwith, of any accident or incident which has or may have resulted in the release of a biological agent which could cause severe human disease; and

(b) as soon as practicable thereafter, of

(i) the causes of such an accident or incident; and

(ii) the measures taken or to be taken to rectify the situation.

List of employees exposed to certain biological agents

11.—(1) Subject to paragraph 2(1), every employer shall keep a list of employees exposed to a Group 3 or Group 4 biological agent, indicating the type of work done and, where known, the biological agent to which they have been exposed, and records of exposures, accidents and incidents, as appropriate.

(2) Subject to sub-paragraph (3) below, the list shall be kept for at least 10 years following the last known exposure of the employee concerned.

(3) In the case of those exposures which may result in infections—

(a) with biological agents known to be capable of establishing persistent or latent infections;

(b) that, in the light of present knowledge, are undiagnosable until illness develops many years later;

(c) that have particularly long incubation periods before illness develops;

(d) that result in illnesses which recrudesce at times over a long period despite treatment; or

(e) that may have serious long-term sequelae,

the list shall be kept for 40 years following the last known exposure.

(4) The employment medical adviser or appointed doctor referred to in regulation 11, and any employee of that employer with specific responsibility for the health and safety of his fellow employees, shall have access to the list.

(5) Each employee shall have access to the information on the list which relates to him personally.

Notification of the use of biological agents

12.—(1) Subject to sub-paragraphs (5) and (6) below, an employer shall not store or use for the first time one or more biological agents in Group 2, 3 or 4 at particular premises unless he has notified the Executive in writing of his intention to do so at least 30 days in advance or before such shorter time as the Executive may approve and with that notification has furnished the particulars specified in sub-paragraph (3) below.

(2) Subject to sub-paragraphs (5) and (7) below, notification in accordance with sub-paragraph (1) above shall also be made of the storage or use for the first time of—

(a) each subsequent biological agent where that agent is specified in Part V of this Schedule;

(b) each subsequent Group 3 biological agent where that agent does not have an approved classification.

(3) The particulars to be included in the notification referred to in sub-paragraphs (1) and (2) above shall be—

(a) the name and address of the employer and the address of the premises where the biological agent will be stored or used;

(b) the name, qualifications and relevant experience of any employee of that employer with specific responsibilty for the health and safety of his fellow employees;

(c) the results of the assessment made under regulation 6;

(d) the Group to which the biological agent has been assigned and, if the agent is specified in Part V of this Schedule or is a Group 3 agent which does not have an approved classification, the identity of the agent; and

(e) the preventive and protective measures that are to be taken.

(4) Where there are substantial changes to processes or procedures of importance to health or safety at work which render the original notification invalid the employer shall notify the Executive forthwith in writing of those changes.

(5) Sub-paragraphs (1) and (2) above shall not apply in relation to a particular biological agent where an intention to store or use that biological agent has been previously notified to the Executive in accordance with the Genetically Modified Organisms (Contained Use) Regulations 1992(**1**).

(6) Sub-paragraph (1) above shall not apply to an employer who intends to provide a diagnostic service in relation to Group 2 or Group 3 biological agents, other than those Group 3 agents specified in Part V of this Schedule, unless it will involve a process likely to propagate or concentrate that agent.

(7) Sub-paragraph (2) above shall not apply to an employer who intends to provide a diagnostic service unless it will involve a process likely to propagate or concentrate a biological agent which does not have an approved classification.

Notification of the consignment of biological agents

13.—(1) An employer shall not consign any of the biological agents specified in Part V of this Schedule or anything containing, or suspected of containing, such an agent to any other premises, whether or not those premises are under his ownership or control, unless he has notified the Executive in writing of his intention to do so at least 30 days in advance or before such shorter time as the Executive may approve and with that notification has furnished the particulars specified in sub-paragraph (4) below.

(2) Sub-paragraph (1) above shall not apply where—

(a) the biological agent or material containing or suspected of containing such an agent is being consigned solely for the purpose of diagnosis;

(b) material containing or suspected of containing the biological agent is being consigned solely for the purpose of disposal; or

(c) the biological agent is or is suspected of being present in a human patient or animal which is being transported for the purpose of medical treatment.

(3) Where a biological agent specified in Part V of this Schedule is imported into Great Britain, the consignee shall give the notice required by sub-paragraph (1) above.

(4) The particulars to be included in the notification referred to in sub-paragraph (1) above shall be—

(a) the identity of the biological agent and the volume of the consignment;

(b) the name of the consignor;

(c) the address of the premises from which it will be transported;

(d) the name of the consignee;

(e) the address of the premises to which it shall be transported;

(f) the name of the transport operator responsible for the transportation;

(g) the name of any individual who will accompany the consignment;

(h) the method of transportation;

(i) the packaging and any containment precautions which will be taken;

(j) the route which will be taken; and

(**1**) S.I. 1992/3217.

(k) the proposed date of transportation.

Notification to the Health Ministers

14.—(1) Upon receipt of any notification submitted in accordance with paragraphs 12 or 13 concerning a biological agent specified in Part V of this Schedule, the Executive shall notify the appropriate Health Minister forthwith in writing that that agent is to be or is no longer to be stored, used or consigned.

(2) In sub-paragraph (1) above "Health Minister" means, in respect of England, Scotland or Wales, the Secretary of State concerned with health in that country.

PART II

CONTAINMENT MEASURES FOR HEALTH AND VETERINARY CARE FACILITIES, LABORATORIES AND ANIMAL ROOMS

Containment measures	*Containment levels*		
	2	3	4
1. The workplace is to be separated from any other activities in the same building.	No	Yes	Yes
2. Input air and extract air to the workplace are to be filtered using HEPA or equivalent.	No	Yes, on extract air	Yes, on input and double on extract air
3. Access is to be restricted to authorised persons only.	Yes	Yes	Yes, via air-lock key procedure
4. The workplace is to be sealable to permit disinfection.	No	Yes	Yes
5. Specified disinfection procedures.	Yes	Yes	Yes
6. The workplace is to be maintained at an air pressure negative to atmosphere.	No, unless mechanically ventilated	Yes	Yes
7. Efficient vector control e.g. rodents and insects.	Yes, for animal containment	Yes, for animal containment	Yes

Note:

"Class III cabinet" means a safety cabinet defined as such in BritishStandard 5726: Part I: 1992, or unit offering an equivalent level of operator protection as defined in British Standard 5726: Part I: 1992.

Containment measures	*Containment levels*		
	2	3	4
8. Surfaces impervious to water and easy to clean.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes, for bench, floor, walls and ceiling
9. Surfaces resistant to acids, alkalis, solvents, disinfectants.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes, for bench, floor, walls and ceiling
10. Safe storage of biological agents.	Yes	Yes	Yes, secure storage
11. An observation window, or alternative, is to be present, so that occupants can be seen.	No	Yes	Yes
12. A laboratory is to contain its own equipment.	No	Yes, so far as is reasonably practicable	Yes
13. Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable containment.	Yes, where aerosol produced	Yes, where aerosol produced	Yes (Class III cabinet)
14. Incinerator for disposal of animal carcases.	Accessible	Accessible	Yes, on site

Note:

"Class III cabinet" means a safety cabinet defined as such in BritishStandard 5726: Part I: 1992, or unit offering an equivalent level of operator protection as defined in British Standard 5726: Part I: 1992.

PART III

CONTAINMENT MEASURES FOR INDUSTRIAL PROCESSES

Containment measures	*Containment levels*		
	2	3	4
1. Viable micro-organisms should be contained in a system which physically separates the process from the	Yes	Yes	Yes

Containment measures	*Containment levels*		
	2	3	4
environment (closed system).			
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) biohazard signs should be posted;	Optional	Yes	Yes
(b) (b) access should be restricted to nominated personnel only;	Optional	Yes	Yes, via air-lock
(c) (c) personnel should wear protective clothing;	Yes, work clothing	Yes	Yes, a complete change
(d) (d) decontamination and washing facilities should be provided for personnel;	Yes	Yes	Yes

Containment measures	*Containment levels*		
	2	3	4
(e) (e) 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
(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	Optional	Yes	Yes

Containment measures	*Containment levels*		
	2	3	4
closed system;			
(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

PART IV

BIOHAZARD SIGN

The biohazard sign required by paragraph 6 of Part I of this Schedule shall be in the form shown below—

PART V

LIST OF BIOLOGICAL AGENTS REFERRED TO IN PARAGRAPHS 12(2)(a), 13(1) AND (3) AND 14(1) OF PART I OF THIS SCHEDULE

(1) All Group 4 biological agents.

(2) Rabies virus.

(3) Simian herpes B virus.

(4) Venezuelan equine encephalitis virus.

(5) Tick-borne encephalitis group viruses in Group 3.

(6) Monkeypox virus.

(7) Mopeia virus.