SCHEDULE 3 Regulations 2(1) and 7(6)(a) and (10)

ADDITIONAL PROVISIONS RELATING TO WORK WITH BIOLOGICAL AGENTS

PART I

provisions of general application to biological agents

Interpretation

1. In this Schedule "diagnostic service" means any activity undertaken solely with the intention of 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.

Classification of biological agents

2.—(1) Where a biological agent does not have an approved classification, the employer shall provisionally classify that agent in accordance with sub-paragraph (2), having regard to the nature of the agent and the properties of which he may reasonably be expected to be aware.

(2) 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 more 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.

(3) Where an employer is using a biological agent which has an approved classification and the risk of infection for that particular agent is different from that expected, the employer shall reclassify the agent in consultation with the Executive as if performing a provisional classification under sub-paragraph (2).

Special control measures for laboratories, animal rooms and industrial processes

3.—(1) Every employer who is engaged in any of the activities specified in sub-paragraph (3) 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 as appropriate, taking into account–

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

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

(c) the risk assessment; and

(d) the nature of the biological agent concerned.

(2) An employer who is engaged in–

(a) any of the activities specified in sub-paragraph (3)(a) or (b) shall select measures from Part II;

(b) the activity specified in sub-paragraph (3)(c) shall select measures from Part III and, subject to sub-paragraph (4), when making that selection he may combine measures from different containment levels 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) are–

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

(b) working with 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 working with a Group 2, Group 3 or Group 4 biological agent.

(4) Subject to sub-paragraph (5), the minimum containment level referred to in sub-paragraph (1) shall be–

(a) level 2 for activities which involve working with a Group 2 biological agent;

(b) level 3 for activities which involve working with a Group 3 biological agent;

(c) level 4 for activities which involve working with a Group 4 biological agent;

(d) level 2 for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a biological agent but work with materials in respect of which it is unlikely that a Group 3 or Group 4 biological agent is present;

(e) level 3 or 4, where appropriate, for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a Group 3 or Group 4 biological agent but where the employer knows, or it is likely, that such a containment level is necessary; and

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

(5) The Executive may approve guidelines specifying the minimum containment measures which are to apply in any particular case.

(6) The Executive shall not approve any guidelines under paragraph (5) unless it is satisfied that the health of any person who is likely to be affected by the use of those guidelines will not be prejudiced.

List of employees exposed to certain biological agents

4.—(1) Subject to sub-paragraph (2), 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) Sub-paragraph (1) shall not apply where the results of the risk assessment 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.

(3) The employer shall ensure that the list or a copy thereof is kept available in a suitable form for at least 40 years from the date of the last entry made in it.

(4) The relevant 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

5.—(1) Subject to sub-paragraphs (7) and (8), an employer shall not use for the first time one or more biological agents in Group 2, 3 or 4 at particular premises for any of the activities listed in paragraph 3(3) unless he has–

(a) notified the Executive in writing of his intention to do so at least 20 working days in advance, or such shorter period as the Executive may allow;

(b) furnished with that notification the particulars specified in sub-paragraph (5); and

(c) received the acknowledgement required by sub-paragraph (4).

(2) Subject to sub-paragraphs (7) and (9), an employer shall not use a biological agent which is specified in Part V, except where the use of that agent has been notified to the Executive in accordance with sub-paragraph (1), for any of the activities listed in paragraph 3(3) unless he has–

(a) notified the Executive in writing of his intention to do so at least 20 working days in advance, or such shorter period as the Executive may allow;

(b) furnished with that notification the particulars specified in sub-paragraph (5); and

(c) received the acknowledgement required by sub-paragraph (4).

(3) The Executive may accept a single notification under sub-paragraph (2) in respect of the use of more than one biological agent by the same person.

(4) Upon receipt of the notification required by sub-paragraph (1) or (2), the Executive shall, within 20 working days–

(a) send to the notifier an acknowledgement of receipt; or

(b) if the notification does not contain all of the particulars specified in sub-paragraph (5)–

(i) inform the notifier in writing of the further particulars required, and

(ii) within 10 working days of receipt of those further particulars, send to the notifier an acknowledgement of receipt.

(5) The particulars to be included in the notification referred to in sub-paragraphs (1) and (2) 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 responsibility for the health and safety of his fellow employees;

(c) the results of the risk assessment;

(d) the identity of the biological agent and, if the agent does not have an approved classification, the Group to which the agent has been assigned; and

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

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

(7) Sub-paragraphs (1) and (2) shall not apply in relation to a biological agent where an intention to use that biological agent has been previously notified to the Executive in accordance with the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001(**1**).

(8) The requirement in sub-paragraph (1) to notify first use of a biological agent in Group 2 or 3 shall not apply to an employer whose only use of that agent is in relation to the provision of a diagnostic service provided that use will not involve a process likely to propagate, concentrate or otherwise increase the risk of exposure to that agent.

(9) The requirement in sub-paragraph (2) to notify use of a biological agent specified in Part V shall not apply to an employer whose only use of that agent is in relation to the provision of a diagnostic service provided that use will not involve a process likely to propagate, concentrate or otherwise increase the risk of exposure to that agent.

Notification of the consignment of biological agents

6.—(1) An employer shall not consign a Group 4 biological agent 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).

(2) Sub-paragraph (1) 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 Group 4 biological agent is imported into Northern Ireland, the consignee shall give the notice required by sub-paragraph (1).

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

(k) the proposed date of transportation.

(**1**) S.R. 2001 No. 295

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.	Yes.	Yes.
7. Efficient vector control e.g. rodents and insects.	Yes, for animal containment.	Yes, for animal containment.	Yes.
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.

Containment measures	*Containment levels*		
	2	3	4
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.
14. Incinerator for disposal of animal carcases.	Accessible.	Accessible.	Yes, on site.

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 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	inactivated by validated means.	inactivated by validated chemical or physical means.	inactivated by validated chemical or physical means.

Containment measures	*Containment levels*		
	2	3	4
the viable micro-organisms have been–			
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.
(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	Optional.	Optional.	Yes.

Containment measures	*Containment levels*		
	2	3	4
	be adequately ventilated to minimise air contamination;		
(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 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.

PART IV

BIOHAZARD SIGN

The biohazard sign required by regulation 7(6)(a) shall be in the form shown below–

PART V

BIOLOGICAL AGENTS WHOSE USE IS TO BE NOTIFIED IN ACCORDANCE WITH PARAGRAPH 5(2) OF PART I

Any Group 3 or 4 agent.

The following Group 2 agents–

Bordetella pertussis;

Corynebacterium diphtheriae;

Neisseria meningitides.