
 STATUTORY INSTRUMENTS

1981 No. 1011

HEALTH AND SAFETY

**The Health and Safety (Dangerous Pathogens)
Regulations 1981**

Made - - - - 13th July 1981
Laid before Parliament 20th July 1981
Coming into Operation 1st September 1981

ARRANGEMENT OF REGULATIONS

Regulation

1. Citation and commencement
2. Interpretation
3. Notification of the keeping or handling of listed pathogens
4. Provision relating to laboratories providing a diagnostic service
5. Changes in particulars to be notified
6. Transportation of listed pathogens
7. Notification to the Health Ministers
8. Defence in proceedings for contravening Regulation 3
9. Meaning of "work" and "at work"
10. Modification of section 3(2) of the Health and Safety at Work etc. Act 1974
11. Exemptions

SCHEDULES

- Schedule 1 List of pathogens the keeping or handling of which is to be notified
- Schedule 2 Particulars to be notified in respect of the keeping or handling of a listed pathogen
- Schedule 3 Particulars to be notified in respect of laboratories providing a diagnostic service
- Schedule 4 Particulars to be notified in respect of transportation of a listed pathogen

In exercise of the powers conferred on me by sections 15(1), (2), 3(b), (5)(b) and (6)(b) and 52(2) of, and paragraphs 1(1), 3(1) and 15(1) of Schedule 3 to the Health and Safety at Work etc. Act 1974(a) and of all other powers enabling me in that behalf and for the purpose of giving effect with modifications to proposals submitted by the Health and Safety Commission under section 11(2)(d) of the said Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act and after consult-

(a) 1974 c. 37; section 15(1) was amended by the Employment Protection Act 1975 (c. 71), section 116 and Schedule 15, paragraph 6.

ing with the said Commission in accordance with section 50(2) of that Act, I hereby make the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Health and Safety (Dangerous Pathogens) Regulations 1981 and shall come into operation on 1st September, 1981.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“listed pathogen” means—

- (a) a pathogen listed in Schedule 1,
- (b) a derivative of a pathogen listed in that Schedule which is capable of causing disease in humans,

but does not include any substance in respect of which there is in force a product licence granted under the Medicines Act 1968^(a) or a clinical trial certificate or animal test certificate issued for the purposes of section 31 or 32 of that Act.

“diagnostic service” means any activity carried on with the intention of—

- (a) identifying a listed pathogen,
- (b) isolating or identifying other organisms from specimens or samples suspected of containing a listed pathogen,
- (c) analysing specimens or samples from a patient known to be, or suspected of, harbouring a listed pathogen for purposes relating to the assessment of the clinical progress or assistance in the clinical management of that patient,

and “diagnosis” and “diagnostic work” shall be construed accordingly.

(2) In these Regulations, unless the context otherwise requires, any reference to—

- (a) a self-employed person includes a reference to any person who keeps or handles a listed pathogen and who is not an employer or an employed person in relation to that keeping or handling;
- (b) a numbered Regulation or Schedule is a reference to the Regulation of, or Schedule to, these Regulations bearing that number;
- (c) a numbered paragraph is a reference to the paragraph bearing that number in the Regulation in which the reference appears.

Notification of the keeping or handling of listed pathogens

3.—(1) Subject to paragraph (2), on or after 1st November 1981 an employer or self-employed person shall not keep or handle nor cause or permit the keeping or handling of a listed pathogen unless at least 30 days in advance he has given to the Health and Safety Executive notice in writing of the particulars set out in Schedule 2 in respect of each activity involving that pathogen.

(2) Paragraph (1) shall not apply where—

- (a) the keeping or handling is solely for the purposes of transportation; or
- (b) the listed pathogen is in a human or animal body (whether live or dead) or in any part thereof but this exception shall not apply to any specimen or sample; or

(a) 1968 c. 67.

- (c) the listed pathogen is in the bedding of an infected person or animal or in the clothing of an infected person or in any waste material kept or handled in the course of clinical treatment or post-mortem examination of such a person or animal; or
- (d) the listed pathogen is in a specimen or sample being taken or sent for diagnosis; or
- (e) the keeping or handling is in the course of diagnostic work; or
- (f) the employer or self-employed person, as the case may be, does not know and could not reasonably be expected to know that a listed pathogen is being kept or handled.

Provision relating to laboratories providing a diagnostic service

4.—(1) Subject to paragraph (2), on or after 1st November 1981 an employer or self-employed person shall not carry out a diagnostic service in relation to a listed pathogen unless at least 30 days in advance he has given to the Health and Safety Executive notice in writing of the particulars set out in Schedule 3.

(2) Paragraph (1) shall not apply where the listed pathogen or suspected pathogen is in a human or animal body (whether live or dead).

Changes in particulars to be notified

5. Where—

- (a) there is a change in any of the particulars which have been notified in accordance with Regulation 3(1) or 4(1), or
 - (b) the activities which have been so notified cease to be carried on,
- then the employer or self-employed person, as the case may be, shall notify the Health and Safety Executive forthwith in writing of that change or cessation; but this shall not apply to the completion of a particular activity in accordance with the notification under sub-paragraph (f) of Schedule 2.

Transportation of listed pathogens

6.—(1) Subject to the following provisions of this Regulation, on or after 1st November 1981 a person shall not consign a listed pathogen unless at least 30 days (or such lesser period as the Health and Safety Executive may allow in a particular case) before the pathogen is transported he has notified the Health and Safety Executive in writing of the particulars set out in Schedule 4.

(2) Paragraph (1) shall not apply where—

- (a) the listed pathogen is being consigned—
 - (i) for the purposes of diagnosis, or
 - (ii) within the curtilage of any premises; or
 - (b) the consignor did not know and could not reasonably be expected to know that he was consigning a listed pathogen.
- (3) In the case of a listed pathogen imported into Great Britain, the consignee shall give the notice required by paragraph (1), and paragraph (2)(b) shall have effect as a reference to the consignee not knowing or not reasonably being expected to know that a listed pathogen was being consigned to him.
- (4) In this Regulation “consign” includes send to any other place whether or not it is in the same ownership or control.

Notification to the Health Ministers

7.—(1) Where any notice required by Regulations 3, 4, 5 or 6 is received by the Health and Safety Executive, the Executive shall forthwith give notice in writing of all the particulars included in such notice to the Health Minister for any country within which it appears, from those particulars, that a diagnostic service is to be, or is no longer to be, provided or that a listed pathogen is to be, or is no longer to be, kept or handled or is to be transported.

(2) In this Regulation “Health Minister” means, in respect of England or of Wales or of Scotland, the Secretary of State concerned with health in that country.

Defence in proceedings for contravening Regulation 3

8. In any proceedings for an alleged contravention of Regulation 3 it shall be a defence for the employer or self-employed person, as the case may be, to prove that on discovering that he was unintentionally keeping or handling a listed pathogen or causing or permitting it to be kept or handled, as the case may be, he notified the Health and Safety Executive forthwith.

Meaning of “work” and “at work”

9. For the purposes of Part I of the Health and Safety at Work etc. Act 1974 the meaning of the word “work” shall be extended to include any activity involving the keeping or handling of a listed pathogen and the meaning of “at work” shall be extended accordingly.

Modification of section 3(2) of the Health and Safety at Work etc. Act 1974

10. Section 3(2) of the Health and Safety at Work etc. Act 1974 shall be modified in relation to any person who keeps or handles a listed pathogen so as to have effect as if the reference to a self-employed person included a reference to any person who is not an employer or an employed person in relation to that keeping or handling.

Exemptions

11.—(1) Subject to paragraph (2), the Health and Safety Executive may, by certificate in writing, exempt any person or class of persons, from any of the requirements of these Regulations, and any such exemption may be granted subject to conditions and to a limit of time and may be revoked at any time.

(2) The Executive shall not grant any such exemption unless, having regard to the circumstances of the case, and in particular to—

- (a) the conditions, if any, which it proposes to attach to the exemption, and
- (b) any other requirements imposed by or under any enactments which apply to the case,

it is satisfied that the health and safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it.

Patrick Jenkin,
One of Her Majesty's Principal
Secretaries of State.

13th July 1981.

SCHEDULE 1

Regulation 2(1)

LIST OF PATHOGENS THE KEEPING OR HANDLING OF
WHICH IS TO BE NOTIFIED

Crimean Haemorrhagic Fever virus (Congo)	Marburg virus
Ebola virus	Rabies virus
Junin Haemorrhagic Fever virus	Simian Herpes B virus
Lassa Fever virus	Smallpox virus
Machupo Haemorrhagic Fever virus	Venezuelan Equine Encephalitis virus

SCHEDULE 2

Regulations.3(1) and 5

PARTICULARS TO BE NOTIFIED IN RESPECT OF THE
KEEPING OR HANDLING OF A LISTED PATHOGEN

The particulars to be included in the notice mentioned in Regulation 3(1) shall be—

- (a) the name of the employer or self-employed person responsible for the keeping or handling of the listed pathogen;
- (b) the address of the premises where the pathogen will be kept or handled;
- (c) the location within those premises where the pathogen will be kept or handled;
- (d) the name (including, where relevant, the strain) of the pathogen to be kept or handled;
- (e) the name of the person from whom the pathogen will be obtained and the address of the premises from which it will be obtained;
- (f) particulars of the work to be undertaken, its proposed dates of commencement and completion and whether the listed pathogen is likely to be propagated;
- (g) the name, qualification and relevant experience of—
 - (i) the individual who will be directly in charge of the work,
 - (ii) any other individual who will be personally supervising the work,
 - (iii) any other individual who will be directly involved in the work;
- (h) whether the safety representatives, if any, appointed under the Safety Representatives and Safety Committees Regulations 1977(a) to represent any person who will work with the listed pathogen have been informed of the foregoing particulars.

SCHEDULE 3

Regulation 4(1)

PARTICULARS TO BE NOTIFIED IN RESPECT OF
LABORATORIES PROVIDING A DIAGNOSTIC SERVICE

The particulars to be included in the notice mentioned in Regulation 4(1) shall be—

- (a) the name of the employer or self-employed person responsible for carrying out the diagnostic work;
- (b) the address of the premises where that work will be carried out;
- (c) the location or locations within those premises where that work will be carried out;
- (d) the listed pathogen in respect of which it is intended to provide a diagnostic service;
- (e) whether the safety representatives, if any, appointed under the Safety Representatives and Safety Committees Regulations 1977 to represent any person who will be employed in the diagnostic service have been informed of the foregoing particulars.

(a) S.I. 1977/500.

Regulation 6(1)

SCHEDULE 4

PARTICULARS TO BE NOTIFIED IN RESPECT OF
TRANSPORTATION OF A LISTED PATHOGEN

The particulars to be included in the notice mentioned in Regulation 6(1) shall be—

- (a) the name (including where relevant, the strain), the volume of the consignment and the estimated titre of the listed pathogen;
 - (b) the address of the premises from which it will be transported;
 - (c) the address of the premises to which it will be transported;
 - (d) the name of the consignor;
 - (e) the name of the consignee;
 - (f) the name of the carrier or other transport operator responsible for the transportation;
 - (g) the name of any individual who will accompany the consignment;
 - (h) the route which will be taken;
 - (i) the method of transportation;
 - (j) the packaging and any containment precautions which will be taken;
 - (k) the proposed date of the transportation.
-

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations relate to certain dangerous pathogens (listed in Schedule 1).

The Regulations prohibit the keeping, handling and transportation of a listed pathogen unless notice is given to the Health and Safety Executive at least 30 days in advance; and the carrying on of a diagnostic service, likely to involve a listed pathogen, is prohibited unless similar notice is given. The particulars to be included in a notice are set out in Schedules to the Regulations. The Regulations also require the Executive to pass the information it receives to the appropriate Health Minister.

In addition, for the purposes of Part I of the Health and Safety at Work etc. Act 1974 they extend the meaning of work to include any activity involving the keeping or handling of a listed pathogen; and in relation to such activity provide that section 3(2) of the Act (which relates to general duties of employers and self-employed persons to other persons who are not their employees) shall have effect as if the reference to a self-employed person included a person who is neither an employer nor an employee (Regulations 9 and 10).

SI 1981/1011
ISBN 0-11-017011-3

