Department for Environment Food & Rural Affairs

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Animal Pathogens

Guidance on controls

January 2015

Llywodraeth Cymru
Welsh Government

DOE
Department of the Environment
www.doeni.gov.uk

The Scottish Government
Riaghaltas na h-Alba

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PB 14294

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Introduction

This document contains guidance on the controls on animal pathogens that Defra licences under the SAPO (SAPO) 2008 (Statutory Instrument 944/2008) as amended.

Pathogens are infectious agents, such as viruses, and the control and containment requirements, particularly under SAPO, are to prevent the release or escape of dangerous animal pathogens into the environment where they may cause serious animal or human disease.

The Defra classification for specified animal pathogens is made on the following basis:

- Group 1 - Disease-producing organisms which are enzootic (native in animal in this country) and do not produce notifiable disease.
- Group 2 - Disease producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.
- Group 3 - Disease producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.
- Group 4 - Disease producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.
- Foot and Mouth Disease - Minimum Standards for working with Foot-and-Mouth Disease virus (Group 4)
- Rabies - Special accommodation for Rabies and Rabies related viruses.
- Arthropods – Accommodation for vectors or parasites.

The classification is made for the purpose of protecting animal health from escapes of organisms from laboratories, and not for the protection of workers in those laboratories. Classification of organisms for the purposes of protecting employees under the Control of Substances Hazardous to Health Regulations 2002 (COSHH) is given by the Advisory Committee on Dangerous Pathogens (ACDP) in the Approved List of Biological Agents. The Defra and ACDP classifications are not complementary documents and should not be read as such. Because of this, compliance with one does not absolve employers and their staff from their responsibilities under the other.

The Health and Safety Executive’s (HSE) Biological Agents Unit has a national remit for the inspection programme under the Health and Safety at Work Act in relation to biological agents. HSE undertake the inspection and enforcement functions for specified animal pathogens under Agency agreements with England, Wales and Scotland.

SAPO 2008 (SAPO)

Controls on specified animal pathogens

The SAPO prohibits any person from having in their possession any specified animal pathogen listed in Part I of the Schedule to the Order or any carrier in which they know such a pathogen is present. It also prohibits the introduction into any animal or bird of any pathogen listed in the Schedule to the Order (Parts I and II).

The Order requires any person who has in their possession anything in which they have reasonable grounds for suspecting that a specified animal pathogen in Part 1 of the Schedule to the Order is present, and who does not have a licence in respect of that pathogen, to notify a veterinary inspector immediately. If you need to make such a notification, you should contact the nearest Animal Health Divisional Office. This will be listed in your local telephone directory.

The purpose of the Order is to prevent the introduction and spread into Great Britain of specified animal pathogens which, if introduced, could cause serious disease and economic loss to the British livestock and poultry industries.

The Order has no application to any animal pathogen or carrier contained in licensed veterinary or human medicines.

Licences under SAPO

Licences under the SAPO stipulate the way in which the specified animal pathogens covered by the licence must be handled to ensure their safe containment and disposal, the areas of the laboratory in which various types of work may be done and the persons responsible for supervising the work. Licences are usually valid for 5 years. Re-inspections of laboratories licensed under the SAPO may be carried out at any time to ensure full compliance with licence conditions.

Definitions under SAPO

Under the SAPO "specified animal pathogen" means an animal pathogen listed in the schedule (see below), including:

1. intact pathogens;

2. pathogens which have been attenuated or genetically modified by any means, and

3. any nucleic acid derived from an animal pathogen listed in the Schedule which could produce that pathogen when introduced into a biological system in which the nucleic acid is capable of replicating.

“carrier” means any living creature except man which may carry or transmit a specified animal pathogen or the tissue, cell culture, body fluid, excreta, carcase or part of a carcase of such creature by or by means of which a specified animal pathogen may be transmitted.

List of specified animal pathogens

Specified animal pathogens listed in Part I of the Schedule are:

African horse sickness virus

African swine fever virus

Aujeszky’s disease virus

Avian influenza viruses which are:

(a) uncharacterised; or

(b) Type A viruses which have an intravenous pathogenicity index in six week old chickens of greater than 1.2; or

(c) Type A viruses H5 or H7 subtype for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin

Babesia bovis, B. bigemina and B. caballi

Bacillus anthracis

Bluetongue virus

Bovine leukosis virus

Brucella abortus

Brucella melitensis

Brucella ovis

Brucella suis

Burkholderia mallei

Classical swine fever virus

Cochliomyia hominivorax

Eastern and Western equine encephalomyelitis viruses

Echinococcus multilocularis and Echincoccus granulosus

Ehrlichia ruminantium

Equine infectious anaemia virus

Foot and mouth disease virus

Hendra disease virus

Histoplasma farciminosum

Japanese encephalitis virus

Lumpy skin disease virus

Mycoplasma agalactiae

Mycoplasma capricolum sub species capripneumoniae

Mycoplasma mycoides sub species mycoides SC and mycoides LC variants

Department for Environment, Food and Rural Affairs

Mycoplasma mycoides var capri

Newcastle disease (avian paramyxovirus type 1) viruses which are –

(a) uncharacterised, or

(b) have an intracerebral pathogenicity index in one-day-old chicks of 0.4 or more, when not less than 10 million 50% egg infectious doses (EID50) are administered to each bird in the test.

Nipah disease virus

Peste des petits ruminants virus

Porcine Reproductive and Respiratory Syndrome virus (genotype 2)

Rabies virus and all viruses of the genus Lyssavirus

Rift Valley Fever virus

Rinderpest virus

St Louis equine encephalomyelitis virus

Sheep and goat pox virus

Swine vesicular disease virus

Teschen disease virus

Theileria annulata

Theileria parva

Trichinella spiralis

Trypanosoma brucei, T. congolense, T. equiperdum, T. evansi, T. simiae, and T. vivax

Venezuelan equine encephalomyelitis virus

Vesicular stomatitis virus

West Nile virus

The specified animal pathogen listed in Part II of the Schedule to the Order is:

The live virus causing viral haemorrhagic disease of rabbits.

Applying for a licence under SAPO

If you wish to hold or work with a specified animal pathogen or a carrier of a specified animal pathogen at a laboratory in England, an application form for a licence under the SAPO can be downloaded from the Defra website.

• PATH 1 - Application for a Licence to hold a Specified Animal Pathogen in England

An electronically-completed form may be e-mailed to us but the signed original must also be provided. As the licensing process can take several months to complete, as applicants' laboratories are normally inspected by the HSE, you should allow sufficient time before you propose to start work with the specified pathogen.

The application, which is to be completed for new or additional specified animal pathogens, new or additional laboratories and areas where specified pathogens are to be stored and handled, and for the renewal of licences, must be accompanied by Standard Operating Procedures, and a plan of the site and relevant laboratories/containment areas. Where appropriate, additional information or evidence to support the application should be provided. All documentation is needed before the HSE will consider whether an inspection is needed. This documentation must detail all the operating procedures for work with the specified animal pathogens for which an application has been made. Laboratories are advised to carry out their own risk assessment, and put in place appropriate containment measures before they apply. This will speed up the process. Laboratories must have the necessary trained staff, documented operating procedures and facilities to ensure the safe containment, handling and disposal of the specified animal pathogens concerned. Laboratory inspections will be carried out to assess this.

Forms completed in manuscript and signed should be sent to the Pathogens Licensing Team at Defra. You may fax your application form to us but the signed original must also be provided.

Contact point for applicants who wish to hold and work with a specified animal pathogen in England:

The Pathogens Licensing Team
Defra
Area 5B
17 Smith Square
London
SW1P 3JR
Telephone: 020 7238 3153/6212

Fax: 020 7238 6105

Email: pathogens@defra.gsi.gov.uk

If you wish to hold or work with a specified animal pathogen or carrier in Scotland or Wales please contact the relevant licensing authority at the addresses below.

Scotland

Scottish Executive Environment and Rural Affairs Department
Animal Health and Welfare
Saughton House
Broomhouse Drive
P Spur,
Edinburgh
EH11 3XD
Telephone: 0300 244 9794

E-mail: animal.health@scotland.gsi.gov.uk

Wales

Welsh Assembly Government
Department for Rural Affairs
Cathays Park
Cardiff
CF1 3NQ
Telephone: 02920 823831

Facsimile: 02920 825767

Email: AnimalHealth@wales.gsi.gov.uk

Applying for a transfer licence under SAPO to transfer a specified animal pathogen

Licences issued under the SAPO contain conditions prohibiting any transfer of specified animal pathogens and/or carriers and their derivatives to any other people or laboratories without the prior authority of the Secretary of State. Transfer licences must be obtained to authorise all movements of such material, including movements to ports or airports.

There is no application form for a SAPO transfer licence and a short request letter giving the relevant details is all that is needed. Such letters should be signed by the SAPO licence holder (or a person deputised to take action on the licence holder's behalf such as the institution's Biological Safety Officer) and give the number of the licence. Full details of the proposed transfer should also be provided (e.g. the specified animal pathogens/carriers to be transferred, with quantities and number of containers, the name and address of the person to whom the material is to be transferred and the approximate

transfer date). Where different strains of a specified animal pathogen are included in one transfer these should be separately listed. Requests for transfer licences may be faxed or emailed to us in the first instance but a signed letter should also be provided.

We aim to issue SAPO transfer licences within 15 working days of receipt of the transfer request letter, provided that we do not have to seek additional information from the applicant.

A SAPO transfer licence will not be issued to authorise a domestic movement of a specified animal pathogen or carrier to another laboratory unless the laboratory for which it is destined holds a current SAPO licence for the specified animal pathogen concerned.

Importing specified animal pathogens

When a specified animal pathogen or carrier is being obtained from a country outside the EC, a licence under the Importation of Animal Pathogens Order (IAPO) will be required to authorise the importation. In this case a separate SAPO licence to authorise the movement of the specified animal pathogen from the port of entry to the licence holder's laboratory will not be necessary, as the IAPO licence will authorise this. An IAPO licence authorising the importation of a specified animal pathogen or carrier will only be issued if the applicant holds a licence under the SAPO to hold /work with the specified animal pathogen concerned at their laboratory. To obtain an IAPO licence of this nature follow the link on page 37 and the instructions under section 6.

If a specified animal pathogen or carrier is being sourced from another EC Member State the SAPO licence holder at the receiving laboratory will need to obtain a transfer licence under SAPO to authorise the movement of the specified animal pathogen from the port of entry in England to the licensed laboratory.

Containment Requirements for Laboratories to be Licensed to Handle Pathogens under the SAPO

The containment requirements are intended only as a guide, as decisions on the facilities and procedures required to contain specified animal pathogens safely at individual establishments are made on a case by case basis.

There are separate containment requirements for laboratories that wish to apply to the European Commission to test blood samples from pet cats and dogs under the Pet Travel Scheme.

Group 1

There are no specified animal pathogens in Group 1.

Group 2

Aujeszky’s disease virus
Babesia bigemina
Babesia bovis
Babesia caballi
Bovine leukosis virus
Echinococcus multilocularis
Echinococcus granulosus
Ehrlichia ruminantium
Mycoplasma agalactiae
Mycoplasma capricolum
subspecies capripneumoniae
Mycoplasma mycoides var capri
Mycoplasma mycoides sub species mycoides SC and mycoides LC variants
Theileria annulata
Theileria equi
Theileria parva
Trichinella spiralis
Trypanosoma brucei
Trypanosoma congolense
Trypanosoma equiperdum
Trypanosoma evansi
Trypanosoma simiae
Trypanosoma vivax

Viral haemorrhagic disease of rabbits virus

The following describes the physical features and operating conditions which would be likely to be required by Defra of any laboratory to be licensed to hold or work with Defra Category 2 pathogens. It is concerned with preventing the escape of pathogens from the laboratory and not primarily with ensuring the safety of the workers. It does not in any way limit the obligations placed upon employers and employees by the Health and Safety at Work etc. Act 1974 in general and COSHH in particular, or the Health and Safety

Executive's duty to enforce these obligations. Extra precautions will often be necessary for the safety of the staff.

The laboratory - siting and structure

1. Whereas the laboratory need not be physically separated from other laboratories it should not be sited next to a known fire hazard (e.g. the solvent store) or be in danger of flooding.

2. Access to the laboratory should be limited to laboratory personnel and other specified persons.

3. The entrance to the laboratory should have a clearly defined clean and dirty side over which staff don or remove protective clothing and wash their hands.

4. The laboratory must be proofed against entry or exit of animals or insects. This is particularly important in the case of diseases which can be spread by insect vectors.

5. Liquid effluent containing specified pathogens should be treated by a procedure known to kill the relevant pathogens. Since this procedure may take some time, it may be necessary to have more than one standing tank if work is to be carried out continuously. The standing tank(s) and recording equipment form parts of the facilities of the laboratory, so the Safety Officer is responsible for ensuring their proper functioning.

Laboratory facilities

1. The laboratory must be equipped with a Class I, II or III exhaust protective cabinet where procedures likely to generate aerosols will be used e.g. homogenisation.

2. All waste biological material containing specified pathogens must be sterilised prior to removal from the laboratory site. Therefore, each laboratory should have access to an autoclave. There should be no possibility of removing the load without the autoclave cycle having been completed. As soon as practicable after the completion of the autoclave cycle, the load should be taken to an incinerator and immediately incinerated. Autoclaves should be monitored to ensure that time / temperature cycles are completed and records should be kept.

3. Each member of staff working in the laboratory must have adequate working space.

4. Specified pathogens should be stored in the laboratory and in suitable containers (depending on the mode of storage, frozen or freeze-dried) in a cabinet reserved for specified pathogens and kept under lock and key. A key should be available on demand only to nominated individual(s). Where storage in the laboratory is not reasonably practicable, material must be transported and stored without spillage in properly labelled robust containers which must only be opened in the Category 2 laboratory. Physical security measures similar to those in place at the laboratory must be in place at the site of storage.

Protective clothing

1. Laboratory gowns must wrap over the chest and fit tightly at the wrists. Ordinary white laboratory coats are UNSUITABLE. Staff should have a clean gown for each uninterrupted period spent in the laboratory. Other types of clothing giving the same degree of protection may be acceptable.

2. Gowns must be not be used outside the laboratory suite. They should be autoclaved before they are removed from the laboratory.

3. Gloves must be worn for all work with infective materials and workers must wash hands before leaving the laboratory.

Safety Officer

NOTE: Throughout this document the term Safety Officer refers to a person having responsibility for work with specified pathogens.

1. A Safety Officer able to advise on infectious hazards, and a deputy, must be appointed or designated. The establishment may have a Safety Officer with general responsibility for such hazards. If not, an additional individual must be designated.

2. A Safety Officer should have appropriate qualifications and laboratory experience in working with specified pathogens.

3. The Safety Officer will act as adviser to the Head of the Department in all matters which may affect the containment of the pathogens and should be authorised to stop practices considered unsafe, pending guidance when necessary, from the laboratory Head.

4. He or she will take control, implement first aid in, and investigate all accidents in laboratories and take what other action he considers necessary.

5. Where their responsibilities are not sufficient to warrant their full-time employment as Safety Officer, provided that they are readily accessible to the laboratory during normal hours, they may hold another appointment.

6. He or she will be responsible for the safe storage of specified pathogens and the maintenance of the inventory.

7. He or she will be responsible for organising the admission to the laboratory of cleaners and maintenance personnel and for the disinfection of any apparatus, etc. which is to be removed.

8. He or she will be responsible for advising staff on all aspects of the application of these Safety Precautions.

Training in handling specified pathogens

1. The Safety Officer will organise the initial training of staff in the safe handling of specified pathogens.

2. Training will cover, e.g. the correct use of safety hoods, exhaust protective cabinets, pipettes, syringes / needles, hot / cold rooms, centrifuges, blenders, freeze-driers, shaking machines, ultrasonic disintegrators, glassware and the disposal of contaminated protective clothing and laboratory materials.

3. Staff should only work with specified pathogens if they have some previous experience in microbiology and have had a course of training supervised by the Safety Officer.

Supervision

1. Work in the laboratory must, at all times, be carried out by, or be supervised by, a senior, trained and experienced member of the staff.

2. The supervisor will be personally responsible to the Safety Officer for the safety of the work actually in progress at any time, although he or she may not be responsible for the overall project.

Laboratory discipline

1. The containment area of each laboratory must be identified clearly with appropriate warning notices.

2. When unoccupied, the laboratory must be locked. The key(s) must be kept under the supervision of the Safety Officer, and released only to authorised persons. A key, however, should be kept at a secure control point, available at all times, in case of emergency.

3. In normal hours the supervisor will be responsible to the Safety Officer for ensuring that no unauthorised person enters the laboratory.

4. Only the Safety Officer or his deputy may authorise staff to enter the laboratory, and he or she will hold a list of names of personnel so authorised. Unlisted persons (e.g. visitors, observers, cleaners or maintenance / repair personnel must not enter the laboratory

5. unless they have received a signed statement from the Safety Officer that it is safe for them to do so.

6. The Safety Officer will be responsible for confirming when a laboratory and its apparatus have been disinfected.

7. The laboratory door must be closed whilst work is in progress. No food, drink, tobacco, make-up, etc. may be taken inside. Clean protective clothing should be put on. The 'clean' and 'dirty' areas should be clearly distinguished physically.

8. On the way out, over garments should be removed and before leaving the laboratory the individual must wash hands.

9. This procedure should be adhered to whenever, and for whatever purposes, the room is vacated.

10. All accidents or spillage of potentially dangerous material in the laboratory must be reported IMMEDIATELY to the Safety Office. EVERY SUCH INCIDENT MUST BE REGARDED AS A FULL MEDICAL OR ANIMAL DISEASE HAZARD.

11. The day-to-day cleanliness of the laboratory is the responsibility of those working in it. Only when the Safety Officer has confirmed that it has been disinfected can other cleaning / maintenance work be carried out.

12. At the end of a working day benches and working surfaces should be disinfected.

13. Work with specified animal pathogens must be kept separate at all times from other work in the laboratory.

Handling of specimens

1. All in-coming packages which may contain specified pathogens must be opened by trained staff in the laboratory.

2. Senders should be advised that a liquid sample should be externally identified and sealed in a can filled with sufficient absorbent material wholly to mop up a spill. The can may, if necessary, be cooled in solid carbon dioxide or liquid nitrogen. Similarly solid samples should be double wrapped so that, in the event of the outer container rupturing, there can be no leakage of contents.

3. Chapter 6 of "Laboratory-Acquired Infections" by C H Collins (4th edition, Butterworth and Co. 1999) gives general advice on packing and unpacking specimens, but in the present context all such unpacking must be carried out in the containment facility.

4. Particular care must be taken when biological material which cannot be autoclaved, is to be removed from the laboratory. The Safety Officer must be consulted before unsterilised material is removed. Precautions must be taken to sterilise the outer surface of containers and to sterilise the material itself, as far as possible.

5. The movement of specified pathogens from an approved laboratory to any other premises is prohibited except under the provisions of a licence issued by Defra.

Security

1. It is imperative that the laboratory and animal rooms must be secure against intruders or vandals. An intruder alarm system must be fitted.

2. Security patrols, etc. must not enter laboratories, or animal rooms. If it appears that an adjacent fire or water hazard threatens the room then the Safety Officer should be informed immediately.

3. A key to the laboratory should be held centrally for emergency access but must only be released on the instruction of the Safety Officer or their deputy.

4. The Safety Officer must maintain a list of the specified pathogens used at the laboratory. This list must indicate the number of vials of pathogen under storage.

Standard operating procedures

1. SOPs must be written and issued to staff covering-

a. receipt and unwrapping of incoming specimens;

b. handling of specified pathogens in vitro;

c. handling of specified pathogens in vivo (where appropriate);

d. disposal of all waste and surplus pathogens;

e. storage of specified pathogens; and

f. emergency procedures.

2. All staff must be familiar with these SOPs and have access to them on a day to day basis. Adherence to the SOPs will be a condition of a licence issued under the SAPO and they must not be altered without prior approval from the Defra licensing office. Any plans to amend SOPs must be forwarded, via the Defra inspector, to the appropriate HQ licensing office.

Animal room

NOTE: All relevant regulations in these Safety Precautions apply to any room in which animals are in contact with specified pathogens. There are, in addition, hazards arising from the natural diseases of animals which may be transmissible to man. Diseases can be contacted following bites, scratches, droplet infection or the bites of insect vectors. There are particular hazards associated with the generation of aerosols in animal rooms.

In addition to the staff utilising the animals, others may be engaged to clean and feed them and the Safety Precautions also apply to them.

1.DRAINS: See THE LABORATORY - SITING AND STRUCTURE, paragraph 5.

2.DEAD ANIMALS, BEDDING, DUNG etc.: see LABORATORY FACILITIES, paragraph 2. Where autoclaving followed by incineration would create a radiological hazard, carcases must be first sealed in a suitable bag.

3. CAGES AND ASSOCIATED EQUIPMENT: must be autoclaved or disinfected before being cleaned and returned to store.

4. ESCAPES: in no circumstances should there be a direct exit to the outside. The Safety Officer and the licensing authority of Defra must be informed if an animal cannot be accounted for.

5. VERMIN: suspected or obvious infestation with insects or wild rodents must be reported at once to the Safety Officer and the licensing authority of Defra.

6. MONKEYS: the principal hazard in monkey handling not common to the handling of other animals is the risk of infection with monkey viruses which can produce serious disease in man. The established basic rules for handling must be observed.

7. RESPONSIBILITY: servicing of specified pathogen rooms in the animal house must not be carried out by general animal house staff. Suitably trained staff approved by the Safety

Officer should carry out these duties under the day-to-day supervision of the person in charge of the animal house.

Containment Requirements for Laboratories to be Licensed to Handle Defra Category 3 Pathogens under the SAPO

Group 3

African horse sickness virus
Bacillus anthracis
Bluetongue virus
Brucella abortus
Brucella melitensis
Brucella ovis
Brucella suis
Burkholderia mallei
Classical swine fever virus
Cochliomya hominivorax
Eastern and Western equine encephalomyelitis viruses
Equine infectious anaemia virus
Histoplasma farciminosum
Japanese encephalitis virus
Lumpy skin disease virus
1# Porcine Reproductive and Respiratory Syndrome (PRRS) virus genotype 2 Rift Valley fever virus
St Louis equine encephalomyelitis virus
Sheep and goat pox virus
Venezuelan equine encephalomyelitis virus
2* Vesicular stomatitis virus
West Nile virus

The following describes the physical features and operating conditions which would be required by Defra of any laboratory to be licensed to hold or work with Defra Category 3 pathogens. It is concerned with preventing the escape of pathogens from the laboratory and not primarily with ensuring the safety of the workers. It does not in any way limit the obligations placed upon employers and employees by the Health and Safety at Work etc. Act 1974 in general and COSHH in particular, or the Health and Safety Executive's duty to enforce these obligations. Extra precautions will often be necessary for the safety of the staff.

The laboratory - siting and structure

1. Whereas the laboratory need not be physically separated from other laboratories it should not be sited next to a known fire hazard (e.g. the solvent store) or be in danger of flooding.

2. The laboratory should be isolated by an air lock. A continuous internal air flow must be maintained by one of the following means-

(a) extracting the laboratory air through independent ducting to the outside air through a HEPA filter;

(b) ducting the exhaust air from a microbiological safety cabinet to the outside air through a HEPA filter.

3. In laboratories which have a mechanical air supply system, the supply and extract airflow must be interlocked to prevent positive pressurisation of the room in the event of failure of the extract fan. The ventilation system must also incorporate a means of preventing reverse air flows.

4. The laboratory must be sealable so as to permit fumigation.

1 # PRRS viruses considered not to be of low pathogenicity (Category 3) will include those containing a molecular signature of a 1+29 aa deletion in the nsp2 region of the genome (as described by Lv et al, 2008 a) and those known to result in morbidity and mortality greater than that expected with infection with genotype 1 PRRS viruses endemic in UK. If a genotype 2 PRRS virus is known to be of low pathogenicity, a laboratory may produce evidence to Defra and the HSE to support handling the virus under Defra's category 2 containment conditions.

a An infectious cDNA clone is a highly pathogenic porcine reproductive and respiratory syndrome virus variant associated with porcine high fever syndrome. (Lv, Zhang, Sun et al J Gen Virol 2008;89;2075-2079).

2 * Where small quantities of vesicular stomatitis virus are being handled as part of a plaque assay system for human immunodeficiency viruses, Category 2 containment is sufficient. Any procedures likely to cause aerosols must be performed in a microbiological safety cabinet, and any persons having contact with the virus must not have contact with equidae for 48 hours thereafter. In all other circumstances, Category 3 containment is required.

5. The laboratory must be proofed against entry or exit of animals or insects. This is particularly important in the case of diseases which can be spread by insect vectors.

6. Liquid effluent should be treated by a procedure known to kill the relevant pathogens. This procedure must be confirmed as having operated satisfactorily before the effluent is discharged to the public sewer, e.g. if heat treatment is to be used, temperature recording facilities should be provided to monitor the process. Since treatment and tests may take some time, it may be necessary to have more than one standing tank if work is to be

carried out continuously. The standing tank(s) and recording equipment form parts of the facilities of the laboratory, so the Safety Officer is responsible for ensuring their proper functioning.

Laboratory facilities

1. The laboratory must be equipped with a Class I, II or III exhaust protective cabinet. All laboratory manipulations with live pathogens may be carried out with the cabinet in any

mode with the exception of homogenisation which should be carried out with the cabinet in the Class I or III mode.

2. All waste biological material must be sterilised prior to removal from the laboratory. Therefore, each laboratory should have direct access to an autoclave. There should be no possibility of removing the load without the autoclave cycle having been completed. As soon as practicable after the completion of the autoclave cycle the load should be taken to an incinerator and immediately incinerated. Autoclaves should be monitored to ensure that time / temperature cycles are completed and records should be kept.

3. All waste materials must be made safe before disposal or removal to the incinerator. Where materials cannot be autoclaved, a means must be provided for their immersion in an effective disinfectant.

4. Each member of staff working in the laboratory must have adequate working space.

5. Specified pathogens should be stored in the laboratory and in suitable containers (depending on the mode of storage, frozen or freeze-dried) in a cabinet reserved for specified pathogens and kept under lock and key. A key should be available on demand only to nominated individual(s). Where storage in the laboratory is not reasonably practicable, material must be transported and stored without spillage in properly labelled robust containers which must only be opened in the Category 3 laboratory. Physical security measures similar to those in place at the laboratory must be in place at the site of storage.

Protective clothing

1. Laboratory gowns must wrap over the chest and fit tightly at the wrists. Ordinary white laboratory coats are UNSUITABLE. Staff should have a clean gown for each uninterrupted period spent in the laboratory. Other types of clothing giving the same degree of protection may be acceptable.

2. Gowns must be not be used outside the laboratory suite. They should be autoclaved before they are removed from the laboratory.

3. Gloves must be worn for all work with infective materials and workers must wash hands before leaving the laboratory.

Safety Officer

NOTE: Throughout this document the term Safety Officer refers to a person having responsibility for work with specified pathogens.

1. A Safety Officer able to advise on infectious hazards, and a deputy, must be appointed or designated. The establishment may have a Safety Officer with general responsibility for such hazards. If not, an additional individual must be designated.

2. A Safety Officer should have appropriate qualifications and laboratory experience in working with specified pathogens.

3. The Safety Officer will act as adviser to the Head of the Department in all matters which may affect the containment of the pathogens and should be authorised to stop practices considered unsafe, pending guidance when necessary, from the laboratory Head.

4. He or she will take control, implement first aid in, and investigate, all accidents in laboratories and take what other action he considers necessary.

5. Where their responsibilities are not sufficient to warrant their full-time employment as Safety Officer, provided that they are readily accessible to the laboratory during normal hours, they may hold another appointment.

6. He or she will be responsible for the safe storage of specified pathogens and the maintenance of the inventory.

7. He or she will be responsible for organising the admission to the laboratory of cleaners and maintenance personnel and for the disinfection of any apparatus, etc. which is to be removed.

8. He or she will be responsible for advising staff on all aspects of the application of these Safety Precautions.

Training in handling specified pathogens

1. The Safety Officer will organise the initial training of staff in the safe handling of specified pathogens.

2. Training will cover, e.g. the correct use of safety hoods, exhaust protective cabinets, pipettes, syringes / needles, hot / cold rooms, centrifuges, blenders, freeze-driers, shaking machines, ultrasonic disintegrators, glassware and the disposal of contaminated protective clothing and laboratory materials.

3. Staff should only work with specified pathogens if they have some previous experience in microbiology and have had a course of training supervised by the Safety Officer.

Supervision

1. Work in the laboratory must, at all times, be carried out by, or be supervised by, a senior, trained and experienced member of the staff.

2. The supervisor will be personally responsible to the Safety Officer for the safety of the work actually in progress at any time, although he or she may not be responsible for the overall project.

Laboratory discipline

1. The containment area of each laboratory must be identified clearly with appropriate warning notices.

2. When unoccupied, the laboratory must be locked. The key(s) must be kept under the supervision of the Safety Officer, and released only to authorised persons. A key, however, should be kept at a secure control point, available at all times, in case of emergency.

3. In normal hours the supervisor will be responsible to the Safety Officer for ensuring that no unauthorised person enters the laboratory.

4. Only the Safety Officer or his deputy may authorise staff to enter the laboratory, and he or she will hold a list of names of personnel so authorised.

5. Unlisted persons (e.g. visitors, observers, cleaners or maintenance / repair personnel must not enter the laboratory unless they have received a signed statement from the Safety Officer that it is safe for them to do so.

6. The Safety Officer will be responsible for confirming when a laboratory and its apparatus have been disinfected.

7. The laboratory must be entered through a 'clean-side' changing area (locker room) separated from the 'dirty-side' by an airlock. All clothing, rings, watches, etc. must be removed into a locker. No food, drink, tobacco, make-up, etc. may be taken through the airlock. Clean protective clothing should be put on. The 'clean' and 'dirty' areas should be clearly distinguished physically.

8. On the way out, over garments should be removed on the 'dirty-side' of the airlock. The individual must then wash hands, transfer to the 'clean-side' and dress.

9. This procedure should be adhered to whenever, and for whatever purposes, the room is vacated.

10. All accidents or spillage of potentially dangerous material in the laboratory must be reported IMMEDIATELY to the Safety Office. EVERY SUCH INCIDENT MUST BE REGARDED AS A FULL MEDICAL OR ANIMAL DISEASE HAZARD.

The day-to-day cleanliness of the laboratory is the responsibility of those working in it. Only when the Safety Officer has confirmed that it has been disinfected can other cleaning / maintenance work be carried out.

12. At the end of a working day benches and working surfaces should be disinfected.

13. Work on specified animal pathogens must be kept separate at all times from other work in the laboratory.

14. Periodically, the rooms and everything in them must be fumigated with gaseous formaldehyde.

Handling of specimens

1. All in-coming packages which may contain specified pathogens must be opened by trained staff in the laboratory.

2. Senders should be advised that a liquid sample should be externally identified and sealed in a can filled with sufficient absorbent material wholly to mop up a spill. The can

may, if necessary, be cooled in solid carbon dioxide or liquid nitrogen. Similarly solid samples should be double wrapped so that, in the event of the outer container rupturing, there can be no leakage of contents.

3. Chapter 6 of "Laboratory-Acquired Infections" by C H Collins (4th edition, Butterworth and Co. 1999) gives general advice on packing and unpacking specimens, but in the present context all such unpacking must be carried out in the containment facility.

4. Particular care must be taken when biological material which cannot be autoclaved, is to be removed from the laboratory. The Safety Officer must be consulted before unsterilised material is removed. Precautions must be taken to sterilise the outer surface of containers and to sterilise the material itself, as far as possible.

5. The movement of specified pathogens from an approved laboratory to any other premises is prohibited except under the provisions of a licence issued by Defra.

Security

1. It is imperative that the laboratory and animal rooms must be secure against intruders or vandals. An intruder alarm system must be fitted.

2. Security patrols, etc. must not enter laboratories, or animal rooms. If it appears that an adjacent fire or water hazard threatens the room then the Safety Officer should be informed immediately.

3. A key to the laboratory should be held centrally for emergency access but must only be released on the instruction of the Safety Officer or their deputy.

4. The Safety Officer must maintain a list of the specified pathogens used at the laboratory. This list must indicate the number of vials of pathogen under storage.

Standard Operating Procedures

1. SOPs must be written and issued to staff covering-

(i) receipt and unwrapping of incoming specimens;

(ii) handling of specified pathogens in vitro;

(iii) handling of specified pathogens in vivo (where appropriate);

(iv) disposal of all waste and surplus pathogens;

(v) storage of specified pathogens; and

(vi) emergency procedures.

2. All staff must be familiar with these SOPs and have access to them on a day to day basis. Adherence to the SOPs will be a condition of a licence issued under the SAPO 2008 and they must not be altered without prior approval from the Defra licensing office. Any plans to amend SOPs must be forwarded, via the Defra inspector, to the appropriate HQ licensing office.

Animal room

NOTE: All relevant regulations in these Safety Precautions apply to any room in which animals are in contact with specified pathogens. There are, in addition, hazards arising from the natural diseases of animals which may be transmissible to man. Diseases can be contacted following bites, scratches, droplet infection or the bites of insect vectors. There are particular hazards associated with the generation of aerosols in animal rooms.

In addition to the staff utilising the animals, others may be engaged to clean and feed them and the Safety Precautions also apply to them.

1. DUST: Pre-filters are required to protect the HEPA filters and should be changed as necessary with the air-steam working. Used filters should be immediately placed into bags, autoclaved and then incinerated.

2. DRAINS: See THE LABORATORY - SITING AND STRUCTURE paragraph 6.

3. DEAD ANIMALS, BEDDING, DUNG etc.: see LABORATORY FACILITIES paragraph 2. Where autoclaving followed by incineration would create a radiological hazard, carcases must be first sealed in a suitable bag.

4. CAGES AND ASSOCIATED EQUIPMENT: must be autoclaved or disinfected before being cleaned and returned to store.

5. ESCAPES: in no circumstances should there be a direct exit to the outside. The Safety Officer and the licensing authority of Defra must be informed if an animal cannot be accounted for.

6. VERMIN: suspected or obvious infestation with insects or wild rodents must be reported at once to the Safety Officer and the licensing authority of Defra.

7. MONKEYS: the principal hazard in monkey handling not common to the handling of other animals is the risk of infection with monkey viruses which can produce serious disease in man. The established basic rules for handling must be observed.

8. RESPONSIBILITY: servicing of specified pathogen rooms in the animal house must not be carried out by general animal house staff. Suitably trained staff approved by the Safety Officer should carry out these duties under the day-to-day supervision of the person in charge of the animal house.

Containment Requirements for Laboratories to be Licensed to Handle Defra Category 4 Pathogens under the SAPO 2008.

Group 4

African swine fever virus
Avian influenza viruses which are:
(a) uncharacterised; or
(b) Type A viruses which have an intravenous pathogenicity index in six week old chickens of greater than 1.2; or
(c) Type A viruses H5 or H7 subtype for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin
*Foot and mouth disease virus
Hendra disease virus
Newcastle disease (avian paramyxovirus type 1) viruses which are –
(a) uncharacterised, or
(b) have an intracerebral pathogenicity index in one-day-old chicks of 0.4 or more, when not less than 10 million 50% egg infectious doses (EID50) are administered to each bird in the test Nipah disease virus
Peste des petits ruminants virus
Rinderpest virus
** Rabies virus and all viruses of the genus Lyssavirus
Swine vesicular disease virus
Teschen disease virus
* See Minimum Standards for working with foot and mouth disease virus below.

** Special rabies containment conditions are required – see below.

The following describes the physical features and operating conditions which would be required by Defra of any laboratory to be licensed to hold or work with Defra Category 4 pathogens. It is concerned with preventing the escape of pathogens from the laboratory and not primarily with ensuring the safety of the workers. It does not in any way limit the obligations placed upon employers and employees by the Health and Safety at Work etc. Act 1974 in general and COSHH in particular, or the Health and Safety Executive's duty to enforce these obligations. Extra precautions will often be necessary for the safety of the staff.

The laboratory - siting and structure

1. Whereas the laboratory need not be physically separated from other laboratories it should not be sited next to a known fire hazard (e.g. the solvent store) or be in danger of flooding.

2. The laboratory should be isolated by an air lock and provided with a suitably placed shower. Air locks and rooms must be ventilated by an exhaust air system. The air pressure in the laboratory should be monitored and displayed both within and immediately outside the laboratory. The laboratory should be maintained at a differential negative pressure of 75 Pascal's (Pa) (0.3 inches or 7.6 mm water pressure) to ambient. An alarm should sound if the air pressure falls below this.

The exhaust air must be filtered before discharge through two HEPA filters. The system must include a device to prevent back flow through the filters. The air intake should be protected by a single HEPA filter in case of power failure.

4. The laboratory must be sealable so as to permit fumigation.

5. The laboratory must be proofed against entry or exit of animals or insects. This is particularly important in the case of diseases which can be spread by insect vectors.

6. Effluent should be sterilised by a procedure known to kill the relevant pathogens. This procedure must be confirmed as having operated satisfactorily before the effluent is discharged to the public sewer, e.g. if heat sterilisation is to be used, temperature recording facilities should be provided to monitor the process. Since sterilisation and tests may take some time, it may be necessary to have more than one standing tank if work is to be carried out continuously. The standing tank(s) and recording equipment form parts of the facilities of the laboratory, so the Safety Officer is responsible for ensuring their proper functioning.

Laboratory facilities

1. The laboratory must be equipped with a Class I/II/III exhaust protective cabinet. All laboratory manipulations with live pathogens should be carried out in the cabinet in any mode with the exception of homogenisation which should be carried out with the cabinet in the Class I or Class III mode.

2. All waste biological material must be sterilised prior to removal from the laboratory. Therefore, each laboratory should have direct access to an autoclave which should have double doors. There should be no possibility of removing the load without the autoclave cycle having been completed. As soon as practicable after the completion of the autoclave cycle the load should be taken to an incinerator and immediately incinerated. Autoclaves should be monitored to ensure that time / temperature cycles are completed and records should be kept.

3. All material must be made safe before being removed from the laboratory unit. A double ended dunk tank filled with an effective disinfectant is required for the removal of materials that cannot be autoclaved. The dunk tank should be sealed during fumigation if the disinfectant is incompatible with the fumigant.

4. Each member of staff working in the laboratory must have adequate working space.

5. Specified pathogens should be stored in the laboratory and in suitable containers (depending on the mode of storage, frozen or freeze-dried) in a cabinet reserved for specified pathogens and kept under lock and key. A key should be available on demand only to nominated individual(s).

Protective clothing

1. Laboratory gowns must wrap over the chest and fit tightly at the wrists. Ordinary white laboratory coats are UNSUITABLE. Staff should have a clean gown for each uninterrupted period spent in the laboratory. Other types of clothing giving the same degree of protection may be acceptable.

2. Gowns must be autoclaved before they are removed from the laboratory.

3. Gloves must be worn for all work with infective materials and workers must shower before leaving the laboratory.

Safety Officer

NOTE: Throughout this document the term Safety Officer refers to a person having responsibility for work with specified pathogens.

1. A Safety Officer able to advise on infectious hazards, and a deputy, must be appointed or designated. The establishment may have a Safety Officer with general responsibility for such hazards. If not, an additional individual must be designated.

2. A Safety Officer should have appropriate qualifications and laboratory experience in working with specified pathogens.

3. The Safety Officer will act as adviser to the Head of the Department in all matters which may affect the containment of the pathogens, and should be authorised to stop practices considered unsafe, pending guidance when necessary, from the laboratory Head.

4. He or she will take control, implement first aid in, and investigate, all accidents in laboratories and take what other action he considers necessary.

5. Where their responsibilities are not sufficient to warrant full-time employment as Safety Officer, provided that they are readily accessible to the laboratory during normal hours, they may hold another appointment.

6. He or she will be responsible for the safe storage of specified pathogens and the maintenance of the inventory.

7. He or she will be responsible for organising the admission to the laboratory of cleaners and maintenance personnel and for the disinfection of any apparatus, etc. which is to be removed.

8. He or she will be responsible for advising staff on all aspects of the application of these Safety Precautions.

Training in handling specified pathogens

1. The Safety Officer will organise the initial training of staff in the safe handling of specified pathogens.

2. Training will cover, e.g. the correct use of safety hoods, exhaust protective cabinets, pipettes, syringes / needles, hot / cold rooms, centrifuges, blenders, freeze-driers, shaking machines, ultrasonic disintegrators, glassware and the disposal of contaminated protective clothing and laboratory materials.

3. Staff should only work with specified pathogens if they have some previous experience in microbiology and have had a course of training supervised by the Safety Officer.

Supervision

1. Work in the laboratory must, at all times, be carried out by or be supervised by a senior, trained and experienced member of the staff.

2. The supervisor will be personally responsible to the Safety Officer for the safety of the work actually in progress at any time, although he or she may not be responsible for the overall project.

Laboratory discipline

1. The containment area of each laboratory must be identified clearly with appropriate warning notices.

2. When unoccupied, the laboratory must be locked. The key(s) must be kept under the supervision of the Safety Officer, and released only to authorised persons. A key, however, should be kept at a secure control point, available at all times, in case of emergency.

3. In normal hours the supervisor will be responsible to the Safety Officer for ensuring that no unauthorised person enters the laboratory.

4. Only the Safety Officer or their deputy may authorise staff to enter the laboratory, and he or she will hold a list of names of personnel so authorised.

5. Unlisted persons (e.g. visitors, observers, cleaners or maintenance / repair personnel must not enter the laboratory unless they have received a signed statement from the Safety Officer that it is safe for them to do so.

6. The Safety Officer will be responsible for confirming when a laboratory and its apparatus have been disinfected.

7. The laboratory must be entered through a 'clean-side' changing area (locker room) separated from the 'dirty-side' by a shower and an airlock. All clothing, rings, watches, etc. must be removed into a locker. No food, drink, tobacco, make-up, etc. may be taken through the airlock. Clean protective clothing should be put on. The 'clean' and 'dirty' areas should be clearly distinguished physically.

8. On the way out, over garments should be placed in a bin on the 'dirty-side' of the showers and all remaining clothing also removed to a bin. The individual must then shower, transfer to the 'clean-side' and dress.

9. This procedure should be adhered to whenever, and for whatever purposes, the room is vacated.

10. All accidents or spillage of potentially dangerous material in the laboratory must be reported IMMEDIATELY to the Safety Office. EVERY SUCH INCIDENT MUST BE REGARDED AS A FULL MEDICAL OR ANIMAL DISEASE HAZARD.

11.The day-to-day cleanliness of the laboratory is the responsibility of those working in it. Only when the Safety Officer has confirmed that it has been disinfected can other cleaning / maintenance work be carried out.

12. At the end of a working day benches and working surfaces should be disinfected.

13. Work on specified animal pathogens must be kept separate at all times from other work in the laboratory.

14. Periodically, the rooms and everything in them must be fumigated with gaseous formaldehyde.

Handling of specimens

1. All in-coming packages which may contain specified pathogens must be opened by trained staff in the laboratory.

2. Senders should be advised that a liquid sample should be externally identified and sealed in a can filled with sufficient absorbent material wholly to mop up a spill. The can may, if necessary, be cooled in solid carbon dioxide or liquid nitrogen. Similarly solid

samples should be double wrapped so that, in the event of the outer container rupturing, there can be no leakage of contents.

3. Chapter 6 of "Laboratory-Acquired Infections" by C H Collins (4th edition, Butterworth and Co. 1999) gives general advice on packing and unpacking specimens, but in the present context all such unpacking must be carried out in the containment facility.

4. Particular care must be taken when biological material which cannot be autoclaved, is to be removed from the laboratory. The Safety Officer must be consulted before unsterilized material is removed. Precautions must be taken to sterilise the outer surface of containers and to sterilise the material itself, as far as possible.

5. The movement of specified pathogens from an approved laboratory to any other premises is prohibited except under the provisions of a licence issued by Defra.

Security

1. It is imperative that the laboratory and animal rooms must be secure against intruders or vandals. An intruder alarm system must be fitted.

2. Security patrols, etc. must not enter laboratories, or animal rooms. If it appears that an adjacent fire or water hazard threatens the room then the Safety Officer should be informed immediately.

3. A key to the laboratory should be held centrally for emergency access but must only be released on the instruction of the Safety Officer or their deputy.

4. The Safety Officer must maintain a list of the specified pathogens used at the laboratory. This list must indicate the number of vials of pathogen under storage.

Standard Operating Procedures (SOPs)

1. SOPs must be written and issued to staff covering-

(i) receipt and unwrapping of incoming specimens;

(ii) handling of specified pathogens in vitro;

(iii) handling of specified pathogens in vivo (where appropriate);

(iv) disposal of all waste and surplus pathogens;

(v) storage of specified pathogens; and

(vi) emergency procedures.

2. All staff must be familiar with these SOPs and have access to them on a day to day basis. Adherence to the SOPs will be a condition of a licence issued under the SAPO 2008

and they must not be altered without prior approval from the Defra licensing office. Any plans to amend SOPs must be forwarded, via the Defra inspector, to the appropriate HQ licensing office.

Animal room

NOTE: All relevant regulations in these Safety Precautions apply to any room in which animals are in contact with specified pathogens. There are, in addition, hazards arising from the natural diseases of animals which may be transmissible to man. Diseases can be contacted following bites, scratches, droplet infection or the bites of insect vectors. There are particular hazards associated with the generation of aerosols in animal rooms.

In addition to the staff utilising the animals, others may be engaged to clean and feed them and the Safety Precautions also apply to them.

1. DUST: Pre-filters are required to protect the HEPA filters and should be changed as necessary with the air-steam working. Used filters should be immediately placed into bags, autoclaved and then incinerated.

2. DRAINS: See THE LABORATORY - SITING AND STRUCTURE paragraph 6.

3. DEAD ANIMALS, BEDDING, DUNG etc.: see LABORATORY FACILITIES paragraph 2. Where autoclaving followed by incineration would create a radiological hazard, carcases must be first sealed in a suitable bag.

4. CAGES AND ASSOCIATED EQUIPMENT: must be autoclaved or disinfected before being cleaned and returned to store.

5. ESCAPES: in no circumstances should there be a direct exit to the outside. The Safety Officer and the licensing authority of Defra must be informed if an animal cannot be accounted for.

6. VERMIN: suspected or obvious infestation with insects or wild rodents must be reported at once to the Safety Officer and the licensing authority of Defra.

7. MONKEYS: the principal hazard in monkey handling not common to the handling of other animals is the risk of infection with monkey viruses which can produce serious disease in man. The established basic rules for handling must be observed.

8. RESPONSIBILITY: servicing of specified pathogen rooms in the animal house must not be carried out by general animal house staff. Suitably trained staff approved by the Safety Officer should carry out these duties under the day-to-day supervision of the person in charge of the animal house.

FMD Minimum Standards

Minimum Standards for Laboratories to be licensed to handle Foot-and-Mouth Disease virus under the SAPO 2008

Laboratories wishing to handle foot and mouth disease virus must be approved by Defra and be listed in Council Directive 2003/85/EC on Community measures for the control of foot and mouth disease. This means that these laboratories must operate at least in accordance with international minimum standards. These standards have recently been amended.

Laboratories working with Foot-and-Mouth Disease virus must meet or exceed the standards set out in the “Minimum Standards for Laboratories working with FMD in vitro/in vivo 2009”. This Standard was adopted by the 38th General Session of the European Commission for the Control of Foot-and-Mouth Disease on 30th April 2009.

Member States have agreed amendments to Council Directive 2003/85/EC to update references to this Standard which were published on 2 December 2009 (European Commission Decision 2009/869/EC).

Containment Requirements for Laboratories to be Licensed to Handle Rabies Virus Under the SAPO 2008

The following describes the physical features and operating conditions which would be required by Defra of any laboratory to be licensed to hold or work with rabies virus as defined in the Order. It is concerned with preventing the escape of rabies virus from the laboratory and not primarily with ensuring the safety of the workers. It does not in any way

limit the obligations placed upon employers and employees by the Health and Safety at Work etc. Act 1974 in general, and the COSHH 2002 regulations in particular, or the Health and Safety Executive's duty to enforce these obligations. Extra precautions will often be necessary for the safety of the staff.

Liaison with Health and Safety Executive

HSE has enforcement responsibility for the safety of employees working in rabies laboratories under the 1974 Health & Safety at Work etc. Act and also the COSHH 2002

regulations. HSE inspections are carried out routinely by Specialist Microbiology Inspectors from HSE's Biological Agents Unit. Where unsatisfactory conditions are discovered HSE may take enforcement action either by issuing an improvement or prohibition notice or by prosecution. An improvement notice gives a time limit within which faults must be corrected; a prohibition notice may stop work with rabies virus with immediate effect.

The contact at HSE is the Principal Specialist Inspector (Biological Agents Unit), Health and Safety Executive, Magdalen House, Stanley Precinct, Bootle, Merseyside L20 3QZ. The telephone number of the Biological Agents Unit is 0151 951 4831.

The laboratory - siting and structure

1. Whereas the laboratory need not be physically separated from other laboratories it should not be sited next to a known fire hazard (e.g. the solvent store) or be in danger of flooding.

2. The laboratory should be isolated by an air lock and provided with a suitably placed shower. Air locks and rooms must be ventilated by an exhaust air system. The air pressure in the laboratory should be monitored and displayed both within and immediately outside the laboratory. The laboratory should be maintained at a differential negative pressure of 75 Pascal's (Pa) (0.3 inches or 7.6 mm water pressure) to ambient. An alarm should sound if the air pressure becomes unacceptable.

3. The exhaust air must be filtered before discharge through two HEPA filters. The system must include a device to prevent back flow through the filters. The air intake should be protected by a single HEPA filter in case of power failure.

4. The laboratory must be sealable so as to permit fumigation.

5. The laboratory must be proofed against entry or exit of animals or insects.

6. Effluent should be held in a standing tank and sterilised by a procedure known to kill rabies virus. This procedure must be confirmed as having operated satisfactorily before the effluent is discharged to the public sewer, e.g. if heat sterilisation is to be used, temperature recording facilities should be provided to monitor the process. Since sterilisation and tests may take some time, it will be necessary to have more than one

Laboratory facilities

1. The laboratory must be equipped with a Class I/III exhaust protective cabinet. All laboratory manipulations with live rabies virus and diagnostic material should be carried

out with the cabinet in the Class I mode with the exception of homogenisation which should be carried out with the cabinet in the Class III mode.

2. All waste biological material must be sterilised prior to removal from the laboratory. Therefore, each laboratory should have direct access to an autoclave which should have double doors. There should be no possibility of removing the load without the autoclave cycle having been completed. As soon as practicable after the completion of the autoclave cycle the load should be taken to an incinerator and immediately incinerated. Autoclaves should be monitored to ensure that time / temperature cycles are completed and records should be kept.

3. Each member of staff working in the laboratory must have adequate working space.

4. Rabies virus must be stored in the laboratory and in suitable containers (depending on the mode of storage, frozen or freeze-dried) in a cabinet reserved for rabies virus and kept under lock and key. A key should be available on demand only to nominated individual(s).

Protective clothing

1. Laboratory gowns must wrap over the chest and fit tightly at the wrists. Ordinary white laboratory coats are UNSUITABLE. Staff should have a clean gown for each uninterrupted period spent in the laboratory. Other types of clothing giving the same degree of protection may be acceptable.

2. Gowns must be autoclaved before they are removed from the laboratory.

3. Gloves must be worn for all work with infective materials and workers must shower before leaving the laboratory.

4. Special protective clothing is needed in particular circumstances, for example for animal inoculation and when there are hazards from splashes or aerosols. Depending on the nature of the work, it may be necessary to use face-shields, caps, plastic or other protective clothing, or respirators (a sterilisable full-face type with a high-efficiency filter complying with European Normative Standard EN 136:1998). As an alternative to a

respirator, particularly for those with beards, it may be preferable to use a ventilated helmet; some types require a supply of compressed air.

Safety Officer

NOTE: Throughout this document the term Safety Officer refers to a person having responsibility for work with rabies virus.

1. A Safety Officer able to advise on infectious hazards, and a deputy, must be appointed or designated. The establishment may have a Safety Officer with general responsibility for such hazards. If not, an additional individual must be designated.

2. A Safety Officer should have appropriate qualifications and laboratory experience in working with rabies virus.

3. The Safety Officer will act as adviser to the Head of the Department in all matters which may affect the containment of the virus, and should be authorised to stop practices considered unsafe, pending guidance when necessary, from the laboratory Head.

4. He or she will take control, implement first aid in, and investigate, all accidents in laboratories and take what other action he considers necessary.

5. Where their responsibilities are not sufficient to warrant their full-time employment as Safety Officer, provided that they are readily accessible to the laboratory during normal hours, they may hold another appointment.

6. He or she will be responsible for the safe storage of rabies virus and the maintenance of the inventory.

7. He or she will be responsible for organising the admission to the laboratory of cleaners and maintenance personnel and for the disinfection of any apparatus, etc. which is to be removed.

8. He or she will be responsible for advising staff on all aspects of the application of these Safety Precautions.

Training in handling rabies virus

1. The Safety Officer will organise the initial training of staff in the safe handling of rabies virus.

2. Training will cover, e.g. the correct use of safety hoods, exhaust protective cabinets, pipettes, syringes / needles, hot / cold rooms, centrifuges, blenders, freeze-driers, shaking machines, ultrasonic disintegrators, glassware and the disposal of contaminated protective clothing and laboratory materials.

3. Staff should only work with rabies virus if they have some previous experience in microbiology AND have had a course of training supervised by the Safety Officer.

Supervision

1. Two workers are required to work together only during the more hazardous work such as mouse inoculation. Diagnosis and the visual examination and maintenance of inoculated mice may be carried out by a worker working alone provided that in the event of an emergency, a second worker authorised to enter the laboratory can be readily contacted.

2. Work in the rabies virus laboratory must, at all times, be carried out by or be supervised by a senior, trained and experienced member of the staff.

3. The supervisor will be personally responsible to the Safety Officer for the safety of the work actually in progress at any time, although they may not be responsible for the overall project.

Laboratory discipline

1. The containment area of each rabies virus laboratory must be identified clearly with appropriate warning notices.

2. When unoccupied, the laboratory must be locked. The key(s) must be kept under the supervision of the Safety Officer, and released only to authorised persons. A key, however, should be kept at a secure control point, available at all times, in case of emergency.

3. In normal hours the supervisor will be responsible to the Safety Officer for ensuring that no unauthorised person enters the laboratory.

4. Only the Safety Officer or his deputy may authorise staff to enter the laboratory, and he will hold a list of names of personnel so authorised.

5. Unlisted persons (e.g. visitors, observers, cleaners or maintenance / repair personnel must not enter the laboratory unless they have received a signed statement from the Safety Officer that it is safe for them to do so.

6. The Safety Officer will be responsible for confirming when a laboratory and its apparatus have been disinfected.

7. The rabies virus laboratory must be entered through a 'clean-side' changing area (locker room) separated from the 'dirty-side' by a shower and airlock. All clothing, rings, watches, etc. must be removed into a locker. No food, drink, tobacco, make-up, etc. may be taken through the shower area. Clean protective clothing should be put on. Where appropriate, protective over garments including respirator and hood should be worn. Special footwear should be put on just prior to entering the 'dirty' area. The 'clean' and 'dirty' areas should be clearly distinguished physically.

8. On the way out special footwear should be washed in a suitable disinfectant / detergent. Over garments should be placed in a bin on the 'dirty-side' of the showers and all remaining clothing also removed to a bin. The individual must then shower, transfer to the 'clean-side' and dress.

9. This procedure should be adhered to whenever, and for whatever purposes, the room is vacated.

10. All accidents or spillage of potentially dangerous material in the laboratory must be reported IMMEDIATELY to the Safety Office. EVERY SUCH INCIDENT MUST BE REGARDED AS A FULL MEDICAL OR ANIMAL DISEASE HAZARD.

11.The day-to-day cleanliness of the rabies virus laboratory is the responsibility of those working in it. Only when the Safety Officer has confirmed that it has been disinfected can other cleaning / maintenance work be carried out.

12. At the end of a working day benches and working surfaces should be disinfected.

13. Periodically, the rooms and everything in them must be fumigated with gaseous formaldehyde.

Handling of specimens

1. All in-coming packages which may contain rabies must be opened by trained staff in the laboratory.

2. Senders should be advised that a liquid sample should be externally identified and sealed in a tin can filled with sufficient absorbent material wholly to mop up a spill. The can may, if necessary, be cooled in solid carbon dioxide or liquid nitrogen. Similarly solid samples should be double wrapped so that, in the event of the outer container rupturing, there can be no leakage of contents.

3. Chapter 6 of "Laboratory-Acquired Infections" by C H Collins (4th edition, Butterworth and Co. 1999) gives general advice on packing and unpacking specimens, but in the present context all such unpacking must be carried out in the containment facility.

4. Particular care must be taken when biological material which cannot be autoclaved, is to be removed from the rabies virus laboratory. The Safety Officer must be consulted before unsterilised material is removed. Precautions must be taken to sterilise the outer surface of containers and to sterilise the material itself, as far as possible.

5. The movement of live rabies virus from an approved laboratory to any other premises is prohibited except under the provisions of a licence issued by Defra.

Security

1. It is imperative that the laboratory and animal rooms must be secure against intruders or vandals. An intruder alarm system must be fitted.

2. Security patrols, etc. must not enter laboratories, or animal rooms. If it appears that an adjacent fire or water hazard threatens the room then the Safety Officer should be informed immediately.

3. A key to the laboratory should be held centrally for emergency access but must only be released on the instruction of the Safety Officer or his deputy.

4. The Safety Officer must maintain a list of the rabies strains used at the laboratory and a copy of the list should be deposited with the Defra licensing authority. This list must indicate the number of vials of virus under storage.

Standard Operating Procedures

1. SOPs must be written and issued to staff covering-

(i) receipt and unwrapping of incoming specimens;

(ii) handling of specified pathogens in vitro;

(iii) handling of specified pathogens in vivo (where appropriate);

(iv) disposal of all waste and surplus pathogens;

(v) storage of specified pathogens; and

(vi) emergency procedures.

2. All staff must be familiar with these SOPs and have access to them on a day to day basis. Adherence to the SOPs will be a condition of a licence issued under the SAPO 2008 and they must not be altered without prior approval from the Defra licensing office. Any plans to amend SOPs must be forwarded, via the Defra inspector, to the appropriate HQ licensing office.

Animal room

NOTE: All relevant regulations in these Safety Precautions apply to any room in which animals are in contact with rabies virus. There are, in addition, hazards arising from the natural diseases of animals which may be transmissible to man. Diseases can be contacted following bites, scratches, droplet infection or the bites of insect vectors. There are particular hazards associated with the generation of aerosols in animal rooms.

In addition to the staff utilising the animals, others may be engaged to clean and feed them and the Safety Precautions also apply to them.

1. DUST: Pre-filters are required to protect the HEPA filters and should be changed as necessary with the air-steam working. Used filters should be immediately placed into bags, autoclaved and then incinerated.

2. DRAINS: See THE LABORATORY - SITING AND STRUCTURE paragraph 6.

3. DEAD ANIMALS, BEDDING, DUNG etc.: see LABORATORY FACILITIES paragraph 2. Where autoclaving followed by incineration would create a radiological hazard, carcases must be first sealed in a suitable bag.

4. CAGES AND ASSOCIATED EQUIPMENT: must be autoclaved before being cleaned and returned to store.

5. ESCAPES: in no circumstances should there be a direct exit to the outside. The Safety Officer and the licensing authority of Defra must be informed if an animal cannot be accounted for.

6. VERMIN: suspected or obvious infestation with insects or wild rodents must be reported at once to the Safety Officer and the licensing authority of Defra.

7. MONKEYS: the principal hazard in monkey handling not common to the handling of other animals is the risk of infection with monkey viruses which can produce serious disease in man. The established basic rules for handling must be observed.

8. RESPONSIBILITY: servicing of rabies virus rooms in the animal house must not be carried out by general animal house staff. Suitably trained staff approved by the Safety Officer should carry out these duties under the day-to-day supervision of the person in charge of the animal house.

Arthropods

Containment Requirements for Laboratories to be Licensed to Handle Arthropods Under the SAPO 2008

Arthropod accommodation (vectors or parasites)

If the arthropod is vectoring a specified animal pathogen then the containment condition appropriate for that pathogen will be required in addition to those for the arthropod.

A. Structure

(a) Rearing unit

1. Rearing rooms should be physically separate from other arthropod rearing rooms, from animals which may be infected and from cultures of pathogens.

2. Rearing rooms should have an ante-room arranged so that 2 solid or screened doors, opening into the room and closing automatically, are provided. The ante-room must be large enough to allow one door to be closed before the other is opened. It should also contain an insect-killing device.

3. Internal wall surfaces should be readily washable (e.g. tiles) and light coloured to facilitate detection and destruction of escaped arthropods. Cracks and crevices should be avoided.

4. Air ducts, lights and plumbing fittings and any other openings into the room should be suitably screened or sealed to prevent escape of stray arthropods.

5. For easy cleaning to prevent build-up of residues where arthropods or pathogens may persist, light removable shelving rather than fitted units should be provided.

6. Recapture devices, such as u.v. light electrocution traps, or sticky traps for flying insects, should be provided to prevent the survival of escaped arthropods.

7. Waste disposal outlets must be provided with a fine-mesh sieve to ensure the retention of the smallest larvae or other stages of arthropods in waste water or washings, and permit safe disposal of all solid waste.

8. No crevices or structure (e.g. humidifier) should be able to contain unmonitored sources of open water in which insects such as mosquitoes may oviposit.

9. As an extra precaution, windows and other outlets of rooms leading off an insectary containing insects which may carry or cause disease, should also be screened against flying insects.

b) Experimental rooms and yards

1. Rooms and yards for experimental work with arthropod vectors or parasites should be separate from arthropod-reading accommodation, but should comply with the same basic structural requirements. If large animal hosts, e.g. cattle or sheep, are to be used, these may have to be modified, but this must be done in such a way as to ensure continued security.

2. Within the room, where arthropods carrying pathogens are concerned, fail-safe cages should be employed (e.g. use of safety cabinets for flying insects, or cages over trays of oil or glycerine for crawling arthropods).

3. Protective clothing should be provided as necessary to ensure against infection of operators by accidental arthropod bites, or abrasions, with face mask where necessary to avoid inhalation of pathogenic organisms in dust.

4. Special arrangements may be necessary for the sterilisation or disinfection of solid and liquid waste possibly contaminated by pathogens or infected arthropods.

5. Experimental yards for infested large animals (cattle and sheep) should be arthropod-proof and precautions should be taken against the spread of ectoparasites by birds and rodents. A moat containing disinfectant or acaricide may be necessary where crawling ectoparasites are involved.

B. Procedures

1. All stages of any arthropod should be killed before disposal in a sealed container or bag, using a suitable fumigant.

2. All larvae should be reared in a manner which will prevent the escape of emerging adults. Culturing procedure should be carefully timed where possible, so that the expected emergence date can be marked on cultures.

3. All arthropod cultures should be killed and disposed of as soon as their purpose has been completed.

4. If progeny are reared from virus-infected arthropods, these should be treated at all stages as infected individuals and kept in appropriate accommodation.

5. Small animal vertebrate hosts exposed to infected arthropods within the experimental rooms should be retained in screened accommodation and transferred to it in secure non-breakable containers, which must be sterilised after use.

6. Large animal hosts used for transmission experiments should be kept in screened accommodation, the arthropods involved being transported to and from the host in secure non-breakable containers, which must be sterilised after use.

7. When entering experimental yards containing livestock infested with specified arthropods (e.g. psoroptes mites, some ticks), experimental staff should wear special protective clothing which is left in a store at the entrance to minimise the risk of escape of non-enzootic pests

Importation of Animal Pathogens Order 1980 (IAPO)

For further information see guidance on Bringing non-specified animal pathogens or carriers into the UK.

Customer Service Standards

Service standards – Import licensing of animal pathogens and carriers, licensing of laboratories to hold and work with specified animal pathogens

We are committed to providing a responsive and consistently high quality service. We will ensure that we respond to all queries courteously and helpfully and we are dedicated to greater openness in our dealings with our customers. The following paragraphs set out the standards of service that we aim to provide you.

Licences

The consideration of an application for a licence under SAPO is likely to take several months. In almost every case it will be necessary for Health and Safety Executive (HSE) to inspect the laboratory where the work with specified animal pathogens is intended to be done and your application will not be considered until and unless we are satisfied that the

management, facilities and documented operating procedures comply fully with Defra standards for the safe containment of the category of pathogen concerned.

We will acknowledge your SAPO application within 15 working days of receipt and either ask for more information or inform you that an inspector will be in touch to arrange an inspection date. If we request additional information from you in support of your application, processing will be suspended until the date on which we receive the information requested. We will respond to any correspondence about SAPO applications that are being processed within 15 working days or write to you to explain why we cannot do so.

Once we have all the information we need to consider your application, HSE aim to arrange a laboratory inspection within 3 months. Following the inspection and receipt of confirmation from HSE inspectors that any follow-up action required has been completed to Defra's satisfaction, we will aim to complete our consideration of the licence application and notify the applicant of the outcome within 15 working days.

Answering your telephone calls

We will answer your telephone calls promptly or provide a customer friendly answering service for those calls we are unable to answer. We will return all calls within 1 working day. If the person you are calling is out of the office for more than 1 day, a voicemail message will provide an alternative contact name and telephone number. If it is necessary to transfer your call to another section, we will tell you what is happening and we will give you the name and extension number of the person to whom you are being transferred. When we answer the telephone or make calls to you, we will give you our name and the name of the section within which we work.

Dealing with your correspondence

We aim to provide a full reply to letters within 15 working days, or if this is not possible we will explain to you the reason for the delay. Where the 15 day deadline cannot be met, we will send a holding reply within 5 working days explaining the reason for the delay. When we write to you we will be clear, concise and courteous.

Answering your e-mailed enquiries

We will acknowledge e-mailed correspondence within 1 working day. As with written correspondence, we will send you a reply within 15 working days. Where the 15 day deadline cannot be met, we will send a holding reply within 5 working days explaining the reason for the delay. If the person you have e-mailed is out of the office for more than 1 day, an out of office message will provide an alternative contact name, e-mail address and telephone number. We will use electronic services to communicate with you quickly and effectively.

Availability of information

Where possible we will offer a choice in the way you can access our services and we will ensure that the information we provide is readily understandable. We will use our pages on the Defra website, to provide up-to-date application forms and guidance. Application forms and guidance can also be obtained from the Pathogens Licensing Team at the address provided below.

Meetings

We will be on time for any pre-arranged meetings.

Constructive Feedback

We value and welcome feedback on the services we provide as this helps us to improve our service to you. If you are dissatisfied about the way in which we have dealt with your application, please contact the Pathogens Licensing Team. You can do this by e-mail, letter, fax, or telephone using the details provided at the end of this document. If you feel that your case has not been fully resolved you may then write to:

Defra
Head of Pathogens Licensing Team
Exotic Disease Policy
Area 5B
17 Smith Square
London
SW1P 3JR
Email: pathogens@defra.gsi.gov.uk

It will help us to investigate your case if you set out the facts as fully as possible. Your case will be thoroughly investigated and you will normally receive a full response within 15 working days.

If you remain dissatisfied about the outcome of your complaint or you feel that your complaint has not been fully resolved, you can write to the Department's impartial Complaint Adjudicator in respect of standards of service at

Defra
Area 7C
Nobel House
17 Smith Square
London
SW1P 3JR.
Email: service-standards.adjudicator@defra.gsi.gov.uk .

The team will investigate your complaint and report back to you within 15 working days. If it is not possible to complete investigations within that timescale, he will write to you explaining why and letting you know when you may expect a full response. (Please note that this procedure only covers complaints which relate specifically to Defra's standards of service. Any complaints regarding the Department's policies or the interpretation of EC Regulations or other legislation fall outside the Complaints Adjudicator's remit, and should be addressed to the Head of the relevant Defra Policy Section).

If you are not satisfied with the adjudicator's decision, you may write to a Member of Parliament who may agree to refer your complaint to the Parliamentary and Health Service Ombudsman at: OPHSO, Millbank Tower, London SW1P 4QP.

Monitoring and improving standards

We are dedicated to identifying and serving the needs of our customers. We will consult with our customers on issues that affect them and will ensure customer responses are relayed back to our managers and operational staff so that action can be taken to improve our quality of service. Defra monitors responses to all forms of communications: letters, faxes, telephone calls and e-mails against Departmental standards.

Compliance

We may investigate the accuracy of information provided on licence applications and prosecute any contravention of the SAPO or the conditions laid down in licences issued under those Orders.

We may undertake visits to check compliance with the conditions of licences under the SAPO.

Where we can, we will give some prior notification of our intention to inspect laboratories or other premises.

The Pathogens Licensing Team,
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