

# The Specified Animal Pathogens Order 1998

## Application for a Licence to hold a specified animal pathogen



For Defra Use

Date received:

### Before completing this form, please read the notes below.

1. The Specified Animal Pathogens Order 1998 prohibits any person from having in their possession any specified animal pathogen listed in Part I of the Schedule or any carrier in which he/she knows such a pathogen is present, and from introducing into any animal any pathogen listed in the Schedule, except under the authority of a licence issued by the appropriate Minister.
2. The Order also requires that if any person has in their possession anything in which he/she has reasonable grounds for believing that a specified pathogen in Part 1 of the Schedule may be present and does not hold a licence to handle that pathogen, they must notify a veterinary inspector immediately.
3. The purpose of the Order is to prevent the introduction and spread into Great Britain of specified animal pathogens which are not endemic and which if introduced, would cause serious disease and economic loss to the livestock industry. The Order has no application to any animal pathogen or carrier contained in licensed veterinary or human medicines.
4. Specified Animal Pathogen means an animal pathogen listed below and includes:
  - (a) intact pathogens;
  - (b) pathogens which have been attenuated or genetically modified by any means; and
  - (c) any nucleic acid derived from an animal pathogen listed in the Schedule to the Order which could produce that pathogen when introduced into a biological system in which the nucleic acid is capable of replicating.
5. Pathogens requiring a licence for possession or introduction into an animal:
  - African horse sickness virus;
  - African swine fever virus;
  - Aujeszky's disease virus;
  - Avian influenza viruses which are:
    - a) uncharacterised; or
    - b) Type A viruses with 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 *Echinococcus 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* subspecies *capripneumoniae*;
  - *Mycoplasma mycoides* subspecies *mycoides* SC and *mycoides* LC variants;
  - *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 (EID<sub>50</sub>) are administered to each bird in the test;
  - Nipah disease virus;
  - Peste des petits ruminants virus;
  - 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 equi*;
  - *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 live virus causing viral haemorrhagic disease of rabbits (licence required for introduction into an animal only).

6. Please send the completed form to:

- The Pathogens Licensing Team,  
Defra,  
Area 5A  
17 Smith Square,  
London SW1P 3JR.  
Telephone No. 020 7238 6211/6195  
Fax. 020 7238 6105  
Email: pathogens@defra.gsi.gov.uk

7. If you are located in SCOTLAND or WALES, and wish to apply for a licence to hold a specified animal pathogen please contact:

- **SCOTLAND**  
Scottish Executive Environment  
and Rural Affairs Department,  
Pentland House, Room 350,  
47 Robb's Loan, Edinburgh EH14 1TY.  
Switchboard 0131 556 8400  
Direct Line 0131 244 6405  
Fax. 0131 244 6616
- **WALES**  
National Assembly for Wales  
Agriculture and Rural Affairs Department  
North Core, CP2,  
Cathays Park, Cardiff CF1 3NQ  
Switchboard 02920 826801  
Direct Line 02920 823593  
Fax. 02920 826120

8. Please ensure that the information you have given is correct and sign and date the Declaration at Section XII.

9. **The Data Protection Act 1998**

Any personal data supplied on your application form or provided separately by you in connection with this application will be used to process your application and to produce any licence issued as a result of this application. Such data (and/or data related to any licence subsequently issued) may be disclosed to other Defra divisions and agencies, and to other Government Departments, including the agricultural departments in Scotland and Wales, to assist consideration of your application, or if the material to be imported is subject to control under legislation for which they are responsible. Information provided in this application form or submitted as part of the licensing process may be stored electronically and used for research/statistical purposes.

Defra may be required to release information, including personal data and commercial information, on request under the Environmental Information Regulations, the Code of Practice on Access to Government Information or the Freedom of Information Act 2000. However, Defra will not permit any unwarranted breach of confidentiality nor will we act in contravention of our obligations under the Data Protection Act 1998.

Defra or its appointed agents may use the name, address and other details on your application form to contact you in connection with occasional customer research aimed at improving the services that Defra provides you.

**Please complete Sections I - XII**

**SECTION I - Laboratory identification**

1. Name of applicant

Full postal address of laboratory where the pathogen will be handled or kept.

Postcode:

Tel. no. (incl. nat. dialling code)

Fax no.

E-mail address

Name of person in overall charge of the premises

Position held

2. Have you previously held a licence for a specified animal pathogen? ..... YES  NO

If 'YES', please give the licence number(s) (if known)

**SECTION II – Pathogens for which licence application made (please tick appropriate boxes)**

	<i>In Vitro</i>	<i>In Vivo</i>	Approximate quantity
African horse sickness virus	<input type="checkbox"/>	<input type="checkbox"/>	
African swine fever virus	<input type="checkbox"/>	<input type="checkbox"/>	
Aujeszky's disease virus	<input type="checkbox"/>	<input type="checkbox"/>	
Avian influenza viruses (uncharacterised or pathogenic)	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Babesia bovis</i> , <i>B. bigemina</i> and <i>B. caballi</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Bacillus anthracis</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Bluetongue virus	<input type="checkbox"/>	<input type="checkbox"/>	
Bovine leukosis virus	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Brucella abortus</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Brucella melitensis</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Brucella ovis</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Brucella suis</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Burkholderia mallei</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Classical swine fever virus	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Cochliomyia hominivorax</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Eastern and Western equine encephalomyelitis viruses	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Echinococcus multilocularis</i> and <i>Echinococcus granulosus</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Ehrlichia ruminantium</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Equine infectious anaemia virus	<input type="checkbox"/>	<input type="checkbox"/>	
Foot and mouth disease virus	<input type="checkbox"/>	<input type="checkbox"/>	
Hendra disease virus	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Histoplasma farciminosum</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Japanese encephalitis virus	<input type="checkbox"/>	<input type="checkbox"/>	
Lumpy skin disease virus	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Mycoplasma agalactiae</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Mycoplasma capricolum</i> subspecies <i>capripneumoniae</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Mycoplasma mycoides</i> subspecies <i>mycoides</i> SC and <i>mycoides</i> LC variants	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Mycoplasma mycoides</i> var <i>capri</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Newcastle disease virus (uncharacterised or pathogenic)	<input type="checkbox"/>	<input type="checkbox"/>	
Nipah disease virus	<input type="checkbox"/>	<input type="checkbox"/>	
Peste des petits ruminants virus	<input type="checkbox"/>	<input type="checkbox"/>	
Rabies virus and all viruses of the genus <i>Lyssavirus</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Rift Valley Fever virus	<input type="checkbox"/>	<input type="checkbox"/>	
Rinderpest virus	<input type="checkbox"/>	<input type="checkbox"/>	
St Louis equine encephalomyelitis virus	<input type="checkbox"/>	<input type="checkbox"/>	
Sheep and goat pox virus	<input type="checkbox"/>	<input type="checkbox"/>	
Swine vesicular disease virus	<input type="checkbox"/>	<input type="checkbox"/>	
Teschen disease virus	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Theileria annulata</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Theileria equi</i>	<input type="checkbox"/>	<input type="checkbox"/>	

<i>Theileria parva</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Trichinella spiralis</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Trypanosoma brucei</i> , <i>T. congolense</i> , <i>T. equiperdum</i> , <i>T. evansi</i> , <i>T. simiae</i> and <i>T. vivax</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Venezuelan equine encephalomyelitis virus	<input type="checkbox"/>	<input type="checkbox"/>	
Vesicular stomatitis virus	<input type="checkbox"/>	<input type="checkbox"/>	
West Nile virus	<input type="checkbox"/>	<input type="checkbox"/>	
Live viral haemorrhagic disease of rabbits (Licence only required for introduction into an animal)	<input type="checkbox"/>	<input type="checkbox"/>	

Intended source/ name   
origin of pathogen(s): address

**SECTION III – Personal details**

1. Please give details of the person(s) responsible for supervising work with each pathogen for which the licence application is made:

Pathogen	Name of supervisor	Qualification(s)	Number of years' experience in handling any listed specified animal pathogens

2. Do any of the laboratory personnel who will be handling infected material have contact with susceptible livestock not involved in the proposed work (i.e. those species susceptible to the pathogen)? ..... YES  NO

If 'YES', please give details

Number of other persons involved directly with work on specified animal pathogens

**SECTION IV – Biological security**

Give the names, routine and emergency telephone numbers of persons responsible for biological safety/security at the site.

Name	Status	Routine phone no.	Emergency phone no.

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**SECTION V – Areas of the premises in which specified pathogens will be kept or handled**

1. Give room numbers/names or geographical locations for all areas in which specified pathogens will be kept or handled. Name the pathogen at each of the locations and briefly state the nature of activity. Please provide a plan showing the locations listed.

Location	Pathogen	Activity

2. Please state the proximity and species of the nearest livestock (cattle, sheep, goats, other ruminants, horses, swine, domestic fowls, turkeys, geese, ducks, guinea fowls, pigeons, pheasants, partridges or quails) to the locations indicated above.

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**SECTION VI – Description of work**

Please give a full description of the work to be carried out with each pathogen. The description should include:

- the object of the work;
- the procedures to be employed;
- whether the studies are to be *in vitro* or *in vivo*;
- In the case of *in vitro* work, whether this will include work with tissue cultures.

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**SECTION VII – Laboratory facilities and fittings**

**Complete a separate copy of this section for each laboratory suite in which specified pathogens are to be handled including *in vivo* work in animals.**

1. Specify the laboratory suite
2. Specify the pathogen(s) that will be worked on here
3. Does the laboratory operate to any particular Defra, ACDP or GMO standard. .... YES  NO   
If so, which standard and to what level?
4. Are livestock kept or reared in the buildings? ..... YES  NO   
If 'YES', what?
5. If YES, is the laboratory adequately separated from the animal accommodation? ..... YES  NO
6. Is there a biohazard sign at the entry to the laboratory? ..... YES  NO
7. Is there a security system allowing access to named individuals only and the doors locked at all other times? ..... YES  NO
8. Is the laboratory maintained under negative pressure? ..... YES  NO
9. Is entry through an airlock? ..... YES  NO
10. Is entry through an airlock with mandatory changing and shower facilities? ..... YES  NO
11. Is there single HEPA filtration on air inlets? ..... YES  NO
12. Is there double HEPA filtration on air outlets? ..... YES  NO
13. Is the air extraction system interlocked to prevent positive pressures occurring? ..... YES  NO
14. Are benches and floors impervious, easy to clean and acid/alkaline/solvent/disinfectant resistant? ..... YES  NO
15. Can the laboratory be sealed and fumigated? ..... YES  NO
16. Is an observation window installed so that persons working in the laboratory can be supervised? ..... YES  NO
17. Is the laboratory proofed against entry or exit of animals or insects? ..... YES  NO
18. Describe how all liquid waste, including that from showers, is disposed of:















