 ISSUES OF LICENSING, ACCREDITATION AND AUTHORISATION: THE EXAMPLE OF THE SPECIFIED ANIMAL PATHOGENS ORDER 1998 (SAPO)

Prepared by the United Kingdom

Introduction

1. This paper describes briefly the licensing procedures that apply in the United Kingdom under the Specified Animal Pathogens Order 1998 (SAPO). Guidance notes for animal pathogens licensing are in the process of being drafted for the first time in their own right for a new pathogen licensing website under construction by the Animal Disease Control branch of the Department Environment, Food and Rural Affairs (DEFRA).

Application for a licence to hold a specified animal pathogen

2. The Specified Animal Pathogens Order 1998 prohibits any person from having in their possession any specified animal pathogen listed in the Order or any carrier in which he/she knows that such a pathogen is present, and from introducing into any animal any listed pathogen, except under the authority of a license issued by the appropriate Minister. Licenses are issued by DEFRA in England, the Scottish Executive Environment and Rural Affairs in Scotland, and in Wales by the Agriculture and Rural Affairs Department of the National Assembly for Wales. Separate by similar legislation and arrangements apply in Northern Ireland. The currently listed pathogens are in the annex.

3. The Order also requires that if any person has in their possession anything which they have reasonable grounds for believing that a specified pathogen may be present and they do not hold a license to handle that pathogen, they must notify a veterinary inspector immediately. The purpose of the Order is to prevent the introduction and spread into Great Britain of a specified animal pathogen which is 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.

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4. Under the terms of the Order, a Specified Animal Pathogen means an animal pathogen listed and includes:

- Listed pathogens;
- Pathogens which have been attenuated or genetically modified by any means; and
- Any nucleic acid derived from an animal pathogen listed which could produce that pathogen when introduced into a biological system which it is capable of replicating.

**License Application Form**

5. Section III of the license application form contains fourteen questions that must be answered by an applicant. Completed applications must be submitted at least six weeks before the intended handling. Information required is as follows:

- The address of the premise where the pathogen will be handled or kept.
- Identification of the specific part of the premises where the pathogen will be handled or kept.
- Name of the person responsible for supervising the work to be undertaken.
- A full description of the work to be carried out, which should include the object of the work, the procedures to be employed and whether the series are to be *in vitro* or *in vivo*. In the case of *in vitro* work, whether this will include work with tissue cultures.
- Details of the precautions taken at the laboratory to prevent escape of the pathogen, e.g. structure, air filtration, screens, safety cabinet, glass etc (If more than one laboratory is to be used each one must be named and any differences described.)
- Whether the laboratory conforms to a particular Advisory Committee on Dangerous Pathogens (ACDP)\(^1\) category, and if so which one.
- If *in vivo* studies are planned, the species must be stated along with details of animal accommodation, e.g. conventional loose-box, cages in fully enclosed room with rodent barrier etc.
- An indication of what will happen to test and in-contact animals at the end of the studies. (Such Animals are also subject to the Animals Scientific Procedures Act 1986 which brings it own system of licensing and inspection.)
- The method of disposal of waste and carcases must be described.
- A description of the facilities available for disposal of cultures and other materials which have contained or been in contact with the pathogen.
- The proximity and species of the nearest livestock to the premises holding the pathogen.
- Whether any of the laboratory personnel who will be handling infected material will have contact with susceptible livestock not involved in the proposed work; and,
- Whether the applicant has previously held a license for a specified pathogen, and if yes the number of the license.

6. The facilities used to handle or hold a specified animal pathogen are liable to inspection both before and after a license is issued.

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\(^1\) ACDP is an advisory body to the Health and Safety Commission consisting of academics and representatives from industry.
Annex

PATHOGENS REQUIRING A LICENSE FOR POSSESSION OR INTRODUCTION INTO AN ANIMAL

- African horse sickness virus;
- African swine fever virus;
- Aujesky’s disease virus;
- Avian influence viruses which are:
  a) Uncharacterised; or
  b) Type A viruses with an intravenous pathogenicity index in 6 week old chickens of greater than 1.2; or
  c) Type A viruses H5 or H& subtype for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin.
- Babesia bovi, B.bigemina, B.caballi and B.equi;
- Bacillus anthracis;
- Bluetongue virus;
- Bovine leucosis virus;
- Brucella abortus;
- Brucella melitensis;
- Brucella ovis;
- Brucella suis;
- Burkholderia (Pseudomonas) mallei;
- Classical swine fever virus;
- Cochliomyia hominivorax;
- Cowdria ruminatum;
- Eastern and Western equine encephalomyelitis viruses;
- Echinococcus multilocularis and E.granulosus;
- Equine infectious anaemia virus;
- Equine morbillivirus;
- Foot and mouth 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;
- Mycoplasma mycoides var capri;
- Newcastle disease (avian paramyxovirus type 1) which are:
  a) uncharacterised; or
  b) have an intercerebral pathogenicity index in one day old chicks of 0.4 or more, when less than 10 million 50% egg infectious doses (EID$_{50}$) are administered to each bird in the test;
- Peste de petit ruminants virus;
- Rabies virus and all viruses of the genus Lyssavirus;
- Rift Valley Fever virus;
- Sheep and goat pox virus;
- Swine vesicular disease;
- Teschen disease virus;
- Theleria 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;
- The live virus causing viral haemorrhagic disease of rabbits (license required for introduction into an animal only).