University of St Andrews

Guidance on Work with Pathogens Regulated under the Specified Animal Pathogens Order (Scotland) 2009

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Appendix 1 - Schedule 1 of The Specified Animal Pathogens (Scotland) Order 2009

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1. Introduction

The Specified Animal Pathogens Order (Scotland) 2009 (SAPO) is aimed at controlling the release of pathogens which could have a significant effect on agricultural or wild animal populations. As such, the regulations require specific containment to avoid release of these agents.

The SAPO regulations are now managed by the Health and Safety Executive on behalf of the Scottish Government. Guidance on compliance to the regulations can be found at URL: http://www.hse.gov.uk/pubns/priced/hsg280.pdf

Further guidance on work with SAPO agents can be found at:

Approved list of Biological Agents: Published by Advisory Committee on Dangerous Pathogens, HSE (MISC 208) www.hse.gov.uk/pubns/misc208.htm


ACGM Compendium of Guidance 10/00, Health and Safety Executive (URL: http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/).

2. Definition of SAPO Agents

Animal pathogens are categorised into 4 groups:

- **Group 1** – Disease-producing organisms which are enzootic (native in animals 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.

The regulations cover specifically defined organisms which cause disease in animal populations. These are described in Appendix 1. They include:

- wild type agents identified in Appendix 1,
- attenuated agents even though they may not cause disease,
- genetically modification of agents described in Appendix 1
- any nucleic acid derived from an animal pathogen listed in Appendix 1 which could produce that pathogen when introduced into a biological system in which the nucleic acid is capable of replicating.
Only agents described in Appendix 1 which are categories 2,3 and 4 need to be notified to the HSE under the SAPO regulations.

Where SAPO agents are genetically modified, then both the SAPO and genetically Modified Organisms (Contained Use) Regulations 2014 need to be complied with though only one notification needs to be made.

3. Management of SAPO Agents

There has been a change in the guidance and in the management of SAPO agents in 2015. Previously, SAPO licences were issued to individual workers for work on specified animal pathogens. In 2015, there has been a change in guidance such that there will be one licence, which will define all work on SAPO agents within the University. The licence for work with SAPO agents will now be held by the University’s Vice-Principal Research on behalf of the University.

All work with SAPO agents must have a detailed risk assessment of the work proposed. This risk assessment must:

- Identify the hazards of the agents you propose to work with;
- Who may be at risk;
- The potential consequences if the agents escape into the environment or if experimental animals are infected with this agent, the consequences if the animal escapes from the contained facility
- What control measures will be used to protect workers, and also what procedures will be undertaken to avoid escape of the agent into the environment. This will include any standard operating procedures, which may apply to the work (e.g. following the Code of Practice in category 3 containment laboratories).
- How will work with these agents be monitored / inspected

Where the SAPO agents are not genetically modified, then all work with such SAPO agents must be done using the CHARM system. A completed and signed CHARM form for work with non-genetically modified organisms should then be sent to the local health and safety committee/personnel and then onto the Chemical and Biological Hazards Management Group. Where the work will involve the use of genetically modified SAPO agents, then a form notifying the University of work with genetically modified organisms should be used and this will be processed as other such notifications.

The risk assessment should be signed by all the proposed workers who will undertake this work. It should then be signed by the Principal Investigator who will have responsibility for implementing this risk assessment on a day to day basis.

All work with category 3 SAPO agents must also be approved by the Director of the Category 3 facilities (Prof T.K. Smith). The University does not have the containment facilities to work with category 4 SAPO agents and thus these may not be brought into the University.

The risk assessment for the work with SAPO agents will then be submitted to the local building health and safety committee / personnel for local approval. The application will then be submitted to the University Chemical and Biological Hazards Management Group for
ratification. Such ratification must include the signature of the University Biological Safety Adviser plus a majority of the committee.

Where work on a SAPO agent requires to comply with multiple regulations (e.g. genetic modification of SAPO agent), then only one notification needs to be made to the University, but this notification must clearly identify the multiple regulation requirements).

Work with SAPO agents which are also part of Schedule 5 of the Anti-Terrorism, Crime and Security Act 2001 as modified in The Part 7 of the Anti-terrorism, Crime and Security Act 2001 (Extension to Animal Pathogens) Order 2007 must be notified to the Home Office. This is done by requesting the Director of EHSS undertake this on behalf of the University.

The Director of Environmental, Health and Safety Services, on behalf of the University’s Vice Principal for Research, will notify the Health and Safety Executive of work with SAPO agents for approval of specific projects as required by the Specified Animal Pathogens Order (Scotland) 2009.

All laboratories that work with SAPO agents should have a copy of the University’s ‘Laboratory Code of Practice for Work With Biological Agents’ posted on the door of the laboratory (See Appendix 9 of the University’s Guidance on Chemical and Biological Safety – Part 2 Biological and Genetic Modification Safety URL: http://www.st-andrews.ac.uk/media/environmental-health-and-safety-services/health-and-safety/chemical-and-biological-safety/Biological%20book%202002-06-2011%20Final.pdf )

4. Training

All workers proposing to undertake work with SAPO agents must have a background training in microbiology/molecular/biology. This will give them enough understanding of the potential biological effects of the work they are proposing to undertake. If the workers do not have this background, they should collaborate with somebody who does have this background.

All groups who propose to undertake work with SAPO agents must undertake the University Moodle training programme on Biosafety and complete the associated test (URL: https://moody.st-andrews.ac.uk/moodle/course/view.php?id=4340 ).

Specific training in the use of particular agents should be provided by the Supervisor or arranged from a competent person/company

Where work is to be carried out in category 3 laboratories, the training for work in Category 3 Containment laboratories will also have to be completed. This includes:

   CL3 Personnel will undergo a system of training supervised by the Containment Laboratory Manager until competent. No personnel will be permitted to work alone in the suite until they have completed training and have been authorised to do so by the Containment Laboratory Manager and Professor T.K. Smith.

   A formal training booklet will be issued. Training will comprise:
1. Detailed study and knowledge of local CL3 procedures and the Standard Operating Procedures.
2. Practical demonstrations of equipment.
3. Supervision until competent of all CL3 procedures.
4. Supervision until competent of handling and disposing of containment level 3 pathogens.

There will be a record of training for each CL3 user.

Records of training in biosafety and for work within category 3 laboratories will be held.

5. Importation of Specified Animal Pathogens

The SAPO regulations do not cover the importation of animal pathogens from EU or outside the EU countries. The importation of such agents is controlled by the Importation of Animal Pathogens Order 1980. A licence will be required to import animal (and plant) pathogens from outside the EU. Such licences are obtained from the Animal and Plant Health Agency (APHA). Guidance on the licences required to import animal pathogens from EU countries and for importation of animal pathogens from outside the EU are given at URL: https://www.gov.uk/bringing-non-specified-animal-pathogens-or-carriers-into-the-uk/licenses-you-must-have. Further information on such importation can be obtained from Imports@AHPA.qsi.gov.uk. No licence can be applied for without an appropriate risk assessment being undertaken on the activities proposed. These will have to be approved by the same process as work with SAPO agents. Guidance on such University procedures is available from the Director of EHSS.

6. SAPO Agent Risk Assessments

All work with SAPO agents must have a suitable and sufficient risk assessment which covers all activities being undertaken. Thus any work with genetically modified SAPO agents must have an appropriate genetic modification risk assessment which highlights the risks associated with the SAPO agent.

The risk assessment should be based on the following aspects:

- **6.1 Inherent Hazard of the Pathogen**
  The inherent pathogenicity of the agent is defined by the HSE categorisation of these agents based on the following premises:
  
  - **Group 1** – Disease-producing organisms which are enzootic (native in animals 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.
The hazard ratings of individual agents are published by the HSE/DEFRA/SEERAD and are national categories. Where an agent does not have a national categorisation, you should use the parameters as set above to estimate the hazard of the agent.

It should be remembered that there are often other hazards associated with the work activity (eg chemicals, electrical equipment etc). All these other hazards should also be clearly identified in the risk assessment.

- **6.2 Who is at risk**
The risk assessment should clearly identify who is at risk. This will include workers with the pathogens and other workers within the laboratory. It should also include others who may access the laboratory e.g. cleaners, trades staff, contractors etc.

The risk assessment should also take into account those with health issues which may make them more susceptible to infection the agent where the SAPO agent is zoonotic.

This section should also consider where people live, thus workers who may live on a farm may have more of a chance of spreading an animal pathogen.

- **6.3 Risks of the proposed work activity (Potential probability of the agent causing disease and the potential severity of any disease)**
The risks of a particular operation will depend on many factors which include:

  - **The probability of the pathogen causing disease** – Many pathogens are not stable when dried out or do not form stable aerosols. In these situations, though the pathogen may cause severe disease, the pathogen is easily destroyed and thus there is very little chance of the pathogen being spread. Some pathogens however are very stable (e.g. anthrax spores) which can last for many years in an infective form in the ground, thus the risk from such an agent are much greater as the potential for spread.

  The probability that the infection of one animal can spread should be considered. The route of infection and numbers of agent shed will also determine whether the agent infects a limited number of animal or whether it can form an epidemic through an animal population (e.g. Foot and Mouth Disease).

  - **Potential Severity of the Pathogen** – This will depend on how much of the agent is required to cause disease. Thus an agent which requires a lot of colony forming units (cfu) to cause disease but is low survivability will reduce the potential risks of the agent.

  Also, the potential disease that the pathogen can cause (and the frequency of the most severe disease) should be taken into account.

  - **Modification of the SAPO agents** – The risks of a particular agent may be considerably affected by genetic modification of its genome. This may substantially reduce the risk of infection of animals, but may considerably enhance infection and/or disease severity. Very careful consideration should be give to the possible effects of inserting any gene into a SAPO agents. Any
genes which are known to increase infectivity, increase disease severity, alter
tropism of the agent etc., then these should be considered to have significantly
increased the risk of the agent and it should be considered to have increased
its hazard rating.
Where the effects of the insertion of a particular gene is not fully understood,
then as a precautionary principle, the risk of the operation should be deemed
to have been significantly increased.

- Selection of SAPO Agents Traits – The risk of a particular
- Other agents – The risks of a particular operation should take into account
  other factors within the experiment for example chemicals etc.

The risks of a particular operation/work activity should take these factors into account
to determine the final risks of the operation. This will give you an estimation of the
risk of the operation and the level of containment required for undertaking this work.
Thus a category 2 project will require category 2 containment facilities and a category
3 project will require category 3 containment facilities.

**NOTE:** The University does not have category 4 containment facilities thus no work
with category 4 SAPO agents or work with other SAPO agents which have been
modified to make them category 4 can be undertaken at the University

- **6.4 How the risks will be controlled**

Once the risk categorisation of the work with the SAPO agent has been determined,
then the risk assessment should identify the control measures which need to be
implemented to minimise the risks of the operation.

These should include (this is not a comprehensive list thus workers should consider
including further control measures).

- **Transport of the agent to and from the University** – One of the potential
  routes of spread of a SAPO agent will be during the process of transport. As
  a consequence it is absolutely vital that agents being transport are packaged
correctly and clearly labelled as required by the Carriage of Dangerous Goods
Regulations 2009 and the appropriate ADR, IATA and maritime guidances on
transport and packaging. Only those who have undertaken the ‘Carriage of
Diagnostic and Infectious Substances’ course can package and send
hazardous Category 2 or 3 notifiable SAPO agents.

Only named individuals can receive packages with SAPO category 2 and 3
agents which are enclosed. The packaging should be checked for damage
and potential leaks of infectious agents. If the package has been damaged
and there is the potential for a hazardous animal pathogen or a zoonotic agent
to be released, then the sample should be destroyed by autoclaving after
soaking in an appropriate disinfectant for at least 24 hours to ensure
destruction. The Director of EHSS must be notified of any potentially released
SAPO category 2 or 3 agents.

- **Storage and Security of SAPO agents** - All SAPO category 2 and 3 agents
  and any SAPO agents which are noted in Schedule 5 of the Anti-Terrorism,
Crime and Security Act 2001 (The Part 7 of the Anti-terrorism, Crime and Security Act 2001 (Extension to Animal Pathogens) Order 2007 must be stored in a safe and secure manner. It is recommended that all other SAPO category 2 and 3 agents are stored in a locked area or in a locked fridge/freezer. Access to a room via a swipe card is deemed a secure area but a key locked door which is left open during normal working hours is not deemed a secure area.

A record of use of all SAPO category 3 agents, genetically modified or otherwise should be kept. The record should include quantities used and the quantity disposed.

- **Containment Facilities** – The containment facilities required for specific work on SAPO will depend on the category of the pathogen as defined in the risk assessment. The containment laboratory requirements are defined in the Document entitled: ‘The Management, design and Operation of Microbiological Containment Laboratories’ issued by the Advisory Committee on Dangerous Pathogens (ISBN:0 7176 2034 4) and the document entitled ‘Biological Agents: Managing the risks in laboratories and healthcare premises’ produced by the Advisory Committee on Dangerous Pathogens (2005).

Where work is undertaken in a Category 2 containment laboratory, then precautions should be taken to ensure there is no potential escape of the SAPO agent into the environment and that workers are not exposed to any zoonotic SAPO agents.

Where there is work in the category 3 laboratories, the risk assessment must be approved by the Director of the Category 3 Laboratories. All work in these laboratories must comply with the University’s Code of Practice for Working in Category 3 Laboratories. Where the risk assessment identifies the need for extra precautions within the category 3 laboratory should be discussed with the Director of the Category 3 Laboratories.

- **Aerosols** – All work where there is a potential for viable SAPO pathogens to be made into aerosols should contained. All such work with cultures etc should be undertaken within the appropriate HEPA air filtered microbiological safety cabinets. Where there is the potential for aerosols in other work (e.g. use of centrifuges etc), these should be sealed units and only opened in such microbiological safety cabinets.

- **NOTE:** The three categories of microbiological safety cabinets do NOT correlate to levels of containment (see Topic 5 of URL: [https://moody.st-andrews.ac.uk/moodle/course/view.php?id=4340](https://moody.st-andrews.ac.uk/moodle/course/view.php?id=4340))

- **Good Microbiological Practice** – All workers using SAPO agents must be trained and supervised in good microbiological practice. Good technique and good housekeeping are important processes which contain the release of biological agents. (See ‘Evidence-Based Biosafety: a Review of the Principles and Effectiveness of Microbiological Containment Measures’ by Kimman, T.G., et al. Clinical Microbiology Reviews, 2008, p. 403–425)
Personal Protective Equipment (PPE) – PPE should always be seen as a last resort as primary protection against SAPO pathogens as it only protects the workers wearing it. The risk assessment should identify if PPE is required to be worn eg disposable gloves. If the risk assessment does identify this, then the risk assessment must make it very clear the type of items to be issued and worn eg it must identify the type of disposable gloves to be worn. Where there is work with SAPO pathogens which are easily transmissible, then the PPE should be disposable (and disposed within the containment laboratory). Laboratory coats and eye protection should be worn as standard practice through all laboratories using SAPO agents.

6.5 Disinfection Process

Appropriate disinfection procedures are a vital method for restricting the release of SAPO pathogens. It is however very important that the correct disinfection process is used for individual SAPO pathogens.

Disinfection is not an absolute process by usually a logarithmic reduction in viable cells. It is therefore vital that consideration is given to the number of viable cells which is considered safe to release into the environment. In general, the Health and Safety Executive require that any disinfection process as a minimum reduces the number of viable cells by $10^5$ organisms (see Topic 6, Moodle Training programme on Biosafety URL: https://moody.st-andrews.ac.uk/moodle/course/view.php?id=4340). Highly pathogenic SDAPO agents may have to have a disinfectant that will reduce the number of viable cells (or specific forms of cells eg spores) by a greater number than $10^5$ organisms. This must be part of the risk assessment for the work on the SAPO agents.

Autoclaving - This is the most effective method of disinfection is autoclaving with steam usually at 120oC at 15psi for 30 minutes. This process is a logarithmic reduction in viable cells eg:
Before autoclaving is used, an assessment will have to be undertaken to determine how long and at what temperature the autoclaving process will be needed to reduce viable organisms by $10^5$. This is related to the D Value which is the time and temperature required to reduce viable organisms by $10^1$. As examples, the D Values for some micro-organisms are given below:

### Table 4.3 Microbial heat resistance

<table>
<thead>
<tr>
<th>Vegetative organisms ($\sim 5^\circ C$)</th>
<th>$D$ (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella sp.</td>
<td></td>
</tr>
<tr>
<td>Salmonella Senftenberg</td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td></td>
</tr>
<tr>
<td>Escherichia coli</td>
<td></td>
</tr>
<tr>
<td>Yeasts and moulds</td>
<td></td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
<td></td>
</tr>
<tr>
<td>Campylobacter jejuni</td>
<td></td>
</tr>
<tr>
<td>Bacterial Endospores</td>
<td></td>
</tr>
<tr>
<td>($\sim 10^\circ C$)</td>
<td></td>
</tr>
<tr>
<td>B. stearothermophillus</td>
<td>$D_{121}$</td>
</tr>
<tr>
<td>C. thermosaccharolyticum</td>
<td></td>
</tr>
<tr>
<td>Desulfitomaculans novella</td>
<td></td>
</tr>
<tr>
<td>B. coagulans</td>
<td></td>
</tr>
<tr>
<td>C. botulinum types A &amp; B</td>
<td></td>
</tr>
<tr>
<td>C. sporogenes</td>
<td></td>
</tr>
<tr>
<td>C. botulinum type E</td>
<td></td>
</tr>
<tr>
<td>$D_{81}$</td>
<td></td>
</tr>
<tr>
<td>$D_{110}$</td>
<td></td>
</tr>
</tbody>
</table>

As can be seen, there is a wide variation in the D Values depending on the organisms eg Bacillus stearothermophilus has a $D_{121}$ value of 4.5 minutes for 1 log reduction in viable cells but Salmonella has a $D_{85}$ (ie autoclaving at 65oC) has a value of 0.02 - .25 minutes for a 1 log reduction in viable cells.

**Autoclaving and Incineration** Where a risk assessment identifies that a 5-log reduction in viable organisms does not sufficiently eliminate the potential for clinical symptoms, then SAPO contaminated samples should be autoclaved for transport and then sent for incineration at a suitably licensed plant. It is no longer a requirement that all SAPO contaminated samples are autoclaved and then incinerated. It is part of the risk assessment. Where incineration is not used as a secondary measure then, written evidence will be required to prove that it is not necessary.

- **Chemical Disinfection** - Chemical disinfection process is more variable and will depend on the organisms, the form of the organism (e.g. spores) and also the medium:eg that the organisms is in **Mode of Action of Chemical Disinfectants**

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>Mode of action</th>
<th>Organisms and Forms affected by Chemical Disinfectant</th>
<th>Items which inactivate the Chemical Disinfectant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol – ethanol and isopropanol alcohol</td>
<td>Denatures protein</td>
<td>Effective, albeit slowly, against vegetative bacteria and lipid containing viruses. <strong>NOT EFFECTIVE against</strong> spores, fungi and non-lipid containing viruses.</td>
<td>Alcohol takes a significant amount of time to be effective - Problem with evaporation of the agent</td>
</tr>
<tr>
<td>Disinfectant</td>
<td>Mode of action</td>
<td>Organisms and Forms affected by Chemical Disinfectant</td>
<td>Items which inactivate the Chemical Disinfectant</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Chlorine (hypochlorite, Chloros etc)</td>
<td>Inactivation by chlorine can result from a number of factors: oxidation of sulphydryl enzymes and amino acids; ring chlorination of amino acids; loss of intracellular contents;</td>
<td>Hypochlorites are suitable disinfectants for vegetative bacteria (including mycobacteria), spores, fungi and both lipid containing and non-lipid containing viruses depending on the concentration of chlorine</td>
<td>Inactivated by small quantities of organic matter</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>Alkylates the amino and sulphydryl groups of proteins and ring nitrogen atoms of purine bases</td>
<td>Effective against vegetative bacteria (including mycobacteria), spores, fungi and both lipid and non-lipid containing viruses</td>
<td>Aldehydes are active in the presence of protein and are not inactivated by natural or man-made substances or detergents - NOTE: Glutaraldehyde is a known sensitiser.</td>
</tr>
<tr>
<td>Glutaraldehyde</td>
<td>Alkylations of sulphydryl, hydroxyl, carboxyl, and amino groups of microorganisms</td>
<td>Contact supplier for details</td>
<td>Contact supplier for details</td>
</tr>
<tr>
<td>Hydrogen Peroxide</td>
<td>Hydrogen peroxide works by producing destructive hydroxyl free radicals that can attack membrane lipids, DNA, and other essential cell components.</td>
<td>Contact supplier for details</td>
<td>Contact supplier for details</td>
</tr>
<tr>
<td>Iodine and Iodophors</td>
<td>Disruption of protein and nucleic acid structure and synthesis</td>
<td>Contact supplier for details</td>
<td>Contact supplier for details</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde (OPA) which contains 0.55% 1,2-benzenedicarboxaldehyde (OPA).</td>
<td>OPA and glutaraldehyde interact with amino acids, proteins, and microorganisms.</td>
<td>Contact supplier for details</td>
<td>Contact supplier for details</td>
</tr>
<tr>
<td>Peracetic acid and peracetic acid + H₂O₂ mixture</td>
<td>Denatures proteins, disrupts the cell wall permeability, and oxidizes sulphydryl and sulfur bonds in proteins, enzymes, and other metabolites</td>
<td>Contact supplier for details</td>
<td>Contact supplier for details</td>
</tr>
<tr>
<td>Phenolics</td>
<td>High concentrations, phenol acts by penetrating and disrupting the cell wall and precipitating the cell proteins.</td>
<td>Effective against vegetative bacteria and against lipid containing viruses</td>
<td>Not affected by organic matter. Doesn’t attack metallic items</td>
</tr>
<tr>
<td>Quaternary ammonium disinfectants</td>
<td>Inactivation of energy-producing enzymes, denaturation of essential cell proteins, and disruption of the cell membrane.</td>
<td>Effective against vegetative bacteria, lipid containing viruses and some fungi NOT EFFECTIVE against mycobacteria, spores and non-lipid containing viruses</td>
<td>Easily inactivated</td>
</tr>
<tr>
<td>Potassium peroxymonosulfate (peroxy compounds) eg Virkon</td>
<td>Virkon® S oxidizes sulfur bonds in proteins and enzymes disrupting the function of the cell membrane causing rupturing of the cell wall</td>
<td>General inactivation of all organisms. Virkon produce detail guidance on the organisms that Virkon will be affected by Virkon and at what concentration</td>
<td>Inactivated by high concentrations of organic matter</td>
</tr>
</tbody>
</table>

It is therefore very important that any risk assessment for work with SAPO agents that evidence that a disinfectant works against the agent and the limitations of the disinfectant to be used are recorded.

Evidence of the effectiveness of the disinfectant to be used should be written in the risk assessment. Evidence from a supplier (e.g. Virkon) that the disinfectant will reduce the number of viable cells (in all its possible forms) by $10^5$ can be used for SAPO category 2 agents. When working with SAPO category 3 agents, then local experimental evidence that a chemical disinfectant will work in all forms of the agent and in the media to be used should be recorded in writing in the risk assessment.

All waste from Category 3 Laboratories are routinely autoclaved and then sent for incineration.

7. Inspection Regimes to monitor effectiveness of the Control measures

An annual inspection of the work place using SAPO agents should be undertaken using an appropriate checklist based on the risk assessments of the work with SAPO agents. Written evidence of the inspection should be kept and be made available to any enforcement agency.

The inspection should show:

- The management structure for work with the SAPO agents and show any changes;
- All risk assessments are valid and have been signed by all workers;
- Evidence that microbiological safety cabinets and other Local Exhaust Ventilation has been tested within the last 14 months;
- Accurate records of the storage, use and disposal of SAPO agents;
- Evidence that disinfection processes are working according to the risk assessment;
- Records of autoclaved SAPO agents are available;
- Records of final disposal of any SAPO agents which require incineration as well as autoclaving
  - Housekeeping within the work area
  - Evidence that emergency actions are up to date (e.g. names and telephone numbers etc.)
- Any other matter relating to the work with Category 2 or 3 SAPO agents

The inspection should be undertaken by senior members of staff e.g. the Supervisor (and Director of the Category 3 Laboratories if there is work with a SAPO category 3 agent) and/or a senior Post-doctoral researcher.

All written inspection records should be kept by the School/Unit.
• **Review Process**

All SAPO risk assessments should be inspected on an annual basis. A formal written review of the SAPO risk assessment must be undertaken on a 3 yearly basis. This formal review must be signed and dated by the Supervisor.

Audits of the work with SAPO agents will be undertaken by members of the Chemical and Biological Hazards management Group on behalf of the University.

**8. Out of Hours Working**

Normal working hours are 8.30am-6.00pm Monday to Friday. Personnel wishing to work outside normal working hours must obtain appropriate permission from the School / Unit. Permission to work on SAPO category 2 agents will be provided by the School/Unit. Out of Normal Working hours work with Category 3 SAPO agents must be approved by the Director of the Category 3 Laboratories and will only be granted if a trained CL3 worker or competent colleague will be working in the BMS building for the length of time the person wishes to work in the CL3 laboratory. The out of hours janitors are informed upon entry and exit of all CL3 workers to the Cat 3 during out of hours.

The risk assessment for work with SAPO agents should include the procedures for working safely during Out of Hours. This will include emergency telephone numbers that should be called in the event of an incident.

**9. Dealing with Spillages**

All accidents or spillage of SAPO agent must be reported to the Director of EHSS and local managers (e.g. Director of Category 3 laboratories, Safety Coordinator for the building where the work is being undertaken) using the formal University Accident / Near Miss form (see Appendix 2).

• **Biological spill inside the safety cabinet**

1. Cover spill with an appropriate chemical disinfectant which is know to work against the SAPO agent, wipe up and put waste in red bag. Discard outer gloves to red bag. Then autoclave the red bag if work is with SAPO category 2 agents. If work with category 3 agent - follow the Code of Practice for work in Category 3 Laboratories.
2. Shut down and close the cabinet and tape up.
3. Inform the appropriate person (e.g. Director of the Category 3 Laboratories, Safety Co-ordinator for the building)
4. Fumigate the cabinet with formaldehyde using the appropriate SOP.
5. The hood is vented the following day.
6. The hood is to be thoroughly cleaned with 70% isopropanol.
• Biological spill outside the safety cabinet

• In all cases of spillage outside a safety cabinet within the containment 3 suite, workers should leave immediately, informing other workers within the suite. The Director of Category 3 Laboratories must be contacted immediately on leaving the suite. In the case of a spill inside an item of equipment, the equipment is to be left open if the spill is discovered on opening. Equipment which is closed should remain closed. The procedure for fumigation of the laboratory is then defined in the Code of Practice for Work in Category 3 Laboratories.

• A spillage of a category 2 SAPO agent

1. The spillage should be treated with a chemical disinfectant known to work against the SAPO agent for a specified time period (usually 1 hour).
2. The treated spillage should then be wiped up and all solid contaminated material should be put in an appropriate bag and disposed accordingly.
3. An accident/Near Miss report form should be completed and the Safety Co-ordinator for the building notified. The accident/Near miss report form must be sent to the Director of EHSS who will determine if the spillage of the SAPO agent needs to be reported to the HSE.

• Potential Release of Agent to the Environment

Where a SAPO agent is thought to have been put to drain by mistake, then the local Safety Co-ordinator should be contacted.

A suitable quantity of a chemical disinfectant should be put to the drain to try and reduce the risk of the agent infecting animals outside the School/Unit.

The Director of EHSS must be informed of such a release to the environment as a matter of urgency (e.g. telephone call) so that the HSE can be notified of the release.

10. Medical Emergency Procedures/First Aid

• Skin contamination

1. Affected areas must be thoroughly washed with soap and water.
2. If the skin is broken then:
   a. Stop work immediately
   b. Encourage bleeding
   c. Thoroughly rinse the wound with copious amounts of water, then soap and rinse profusely with water
   d. Dry and cover the wound
3. Report accident immediately and seek medical attention
• **Injury with Exposure to Infectious Material**

A first aider should be called. Any spillage should be left until the person has been moved from the area. Where there is a risk of aerosol contamination to other staff, they should leave immediately and inform the Safety Co-ordinator.

• **Eye/mouth Contamination**

Eye wash stations are available in each working laboratory.

1. The eye(s) / mouth must be thoroughly irrigated with water and the eye(s) should not be rubbed or aggravated.
2. If mouth contamination do not swallow.
3. Seek immediate medical attention.

• **Splashes to clothing**

1. Contaminated protective clothing should be removed, placed in an autoclave bag and autoclaved.
2. If the splash occurs on outside clothing, remove immediately and autoclave. It is therefore prudent to keep a change of clothing on site for use in such an emergency.
3. An emergency shower is located on the ground floor corridor.

11. **Reporting an Accident/Incident**

All accidents and incidents must be reported using the University Accident / Near Miss Form (see appendix 2 and URL: [http://www.st-andrews.ac.uk/media/environmental-health-and-safety-services/health-and-safety/accidents/Accident-Rep-Form.doc](http://www.st-andrews.ac.uk/media/environmental-health-and-safety-services/health-and-safety/accidents/Accident-Rep-Form.doc)) and documented with the School/Unit Safety Co-ordinator (and Director of Category 3 Laboratories), then sent to the Director of EHSS.

**NB. It may be necessary to contact the HSE under RIDDOR legislation, depending on the nature of the incident, via the safety officers of the University.**
### Appendix 1

*Amended from Schedule 1 of The Specified Animal Pathogens (Scotland) Order 2009,*

<table>
<thead>
<tr>
<th>Specified animal pathogen</th>
<th>Hazard group</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>African horse sickness virus</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>African swine fever virus</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Aujesky’s disease virus</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Avian influenza viruses</td>
<td>4</td>
<td>(a) uncharacterised;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Type A viruses which have an intravenous pathogenicity index in six-week-old chickens of greater than 1.2; or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(c) Type A viruses H5 or H7 sub-type for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin.</td>
</tr>
<tr>
<td>Babesia bigemina</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Babesia bovis</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Babesia caballi</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Bacillus anthracis</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Bluetongue virus</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Bovine leucosis virus</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Brucella abortus</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Brucella melitensis</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Brucella ovis</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Brucella suis</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Burkholderia mallei (formerly Pseudomonas mallei)</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Classical swine fever virus</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Cochliomya hominivorax</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Eastern and Western equine encephalomyelitis viruses</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Echinococcus multilocularis</td>
<td>2*</td>
<td></td>
</tr>
<tr>
<td>Specified animal pathogen</td>
<td>Hazard group</td>
<td>Notes</td>
</tr>
<tr>
<td>----------------------------------------------------------------</td>
<td>--------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Echinococcus granulosus</td>
<td>2*</td>
<td></td>
</tr>
<tr>
<td>Ehrlichia ruminantium</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Equine infectious anaemia virus</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Foot and mouth disease virus</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Hendra disease virus</td>
<td>4*</td>
<td></td>
</tr>
<tr>
<td>Histoplasma farcinomorum</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Japanese encephalitis virus</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Lumpy skin disease virus</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Mycoplasma agalactiae</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Mycoplasma capricolum subspecies capripneumoniae</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Mycoplasma mycoides var capri</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Mycoplasma mycoides subspecies mycoides SC and mycoides LC variants</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Newcastle disease (avian paramyxovirus type 1) viruses</td>
<td>4*</td>
<td>Including: (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 infections doses (ED50) are administered to each bird in the test.</td>
</tr>
<tr>
<td>Nipah disease virus</td>
<td>4*</td>
<td></td>
</tr>
<tr>
<td>Porcine reproductive and respiratory syndrome (PPRS) virus genotype 2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Peste des petits ruminants virus</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Rabies virus (including all viruses of the genus Lyssavirus)</td>
<td>4*</td>
<td></td>
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<tr>
<td>Rift Valley fever virus</td>
<td>3*</td>
<td></td>
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<tr>
<td>Rinderpest virus</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>St Louis equine encephalomyelitis virus</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Sheep and goat pox virus</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Swine vesicular disease virus</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Teschen disease virus</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Theileria annulata</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Theileria equi</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Theileria parva</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Trichinella spiralis</td>
<td>2*</td>
<td></td>
</tr>
<tr>
<td>Specified animal pathogen</td>
<td>Hazard group</td>
<td>Notes</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>--------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>Trypanosoma brucei</td>
<td>2*</td>
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</tr>
<tr>
<td>Trypanosoma congoense</td>
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<td></td>
</tr>
<tr>
<td>Trypanosoma equiperdum</td>
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<td></td>
</tr>
<tr>
<td>Trypanosoma evansi</td>
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<td></td>
</tr>
<tr>
<td>Tryanosoma simiae</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Trypanosoma vivax</td>
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<td></td>
</tr>
<tr>
<td>Venezuelan equine encephalomyelitis virus</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Vesicular stomatitis virus</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>West Nile virus</td>
<td>3*</td>
<td></td>
</tr>
<tr>
<td>Live virus causing viral haemorrhagic disease of rabbits</td>
<td>2</td>
<td>This is only applicable if the virus is deliberately injected into rabbits.</td>
</tr>
</tbody>
</table>

Note (*) This specified animal pathogen also has an approved classification in the Approved List of biological agents as referred to in COSHH.
Appendix 2 - Accident / Near Miss Report Form

University of St. Andrews

Report of an Accident, Dangerous Occurrence or Near Miss

Details of the Person Injured or Involved in the Accident, Dangerous Occurrence or Near Miss

Full Name of Person involved in incident, Address plus Post Code And Telephone Number School / Unit

Age

Sex (M or F)

Occupation of Injured Person or Status if not an Employee (e.g. Resident, Visitor)

Date of Incident Time of Incident

Nature of Injury or Incident (e.g. Broken arm, bruising or fire)

Management (Please tick appropriate boxes) No Action taken Ambulance Called

First Aid Only Casualty Taken to Hospital Advised to see Doctor

Admitted to Hospital for more than 24 Hours

Other (please state actions)

Account of Accident, Dangerous Occurrence or Near Miss

Describe what happened, where and how. In the case of an accident, state what the injured person was doing at the time.

Witnesses (Please give names, address and occupation)

In the event of the casualty being absent from normal duties, please fill in the date of the first absence and date of return to work

Date off work Date of Return to Work

Not yet returned from Work Returned to work on full duties Returned to work on modified duties

(if YES, attach details on separate page)

Remedial Action Taken (to be completed by the School / Unit) (Note: All incidents, other than minor incidents, will require a full accident investigation form to be completed).

Name of person making report Signature Date

Name of Safety Co-ordinator Signature Date

On completion, the School / Unit should retain a copy and send a copy to:
1. The Director of Environmental, Health and Safety Services (EHSS);
2. The Person(s) involved in the incident

To Be Completed by EHSS

Accident Investigation required YES NO Date Action Completed

Environmental, Health and Safety Services February 2009