

Biological Security for Pathogens and Toxins

1. Introduction

This guidance is provided to help you understand the biological security controls required for work with scheduled pathogens and toxins. There are concerns that terrorists might use chemical, biological, radiological and nuclear (CBRN) materials as weapons. Therefore to prevent terrorism these dangerous substances which includes selected pathogens, toxins and their genetic materials are regulated by law and must be securely controlled by Schools and the University. Please note that this guidance is only about biological security and any related general security matters should be directed to University Security.

2. Law

Terrorism laws require employers to protect against security risks from work involving dangerous substances by carrying out risk assessments and providing effective controls. The Anti-Terrorism, Crime and Security Act (ATCSA) and related regulations require controls for work with scheduled pathogens, toxins and their genetic materials to prevent terrorism. The controls required under anti-terrorism laws are in addition to those required under health, safety and environmental laws including the Health and Safety at Work Act, Environmental Protection Act, Animal Health Act and Plant Health Act. Guidance on the law and practice relating to biological security is provided by the Home Office (HO), Department for Transport (DFT), National Protective Security Authority (NPSA), Police Scotland, National Counter Terrorism Security Office (NaCTSO) and Protect UK. The National Counter Terrorism Security Office and the Police Counter Terrorism Security Advisers (CTSA) provide advice, monitor and enforce this area of the law. The Department for Transport and their Transport Security Inspectors provide advice, monitor and enforce the law in relation to the national and international transport of high consequence dangerous goods which includes highly hazardous pathogens and toxins.

3. Security Controls for Schedule 5 Pathogens and Toxins

The Anti-Terrorism, Crime and Security Act is aimed at preventing the possession or use by terrorists of selected dangerous substances which includes selected pathogens, toxins and relevant genetic materials. Schedule 5 of the Act designates which dangerous substances are controlled. The Schedule 5 list with accompanying notes is supplied at the end of this document. The definitions of pathogens includes the pathogen itself, any genetic material containing any nucleic acid sequence associated with pathogenicity and any genetically modified organism containing any such sequence. The definitions of toxins includes subunits of the toxin, any genetic material containing any nucleic acid sequence coding for the toxin and any genetically modified organism containing any such sequence. The law requires the University to have effective controls for the security of these dangerous biological

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substances. NaCTSO provides detailed guidance on the security standards which are required for work with Schedule 5 substances in its document on the Security Requirements for Pathogens and Toxins. This guidance has a restricted circulation and is available to relevant managers and safety advisers from the Police Scotland CTSA. The NaCTSO / Protect UK guidance specifies the detailed control measures required including those for physical security, personnel security and information security.

Schools and principal investigators must ensure that all aspects of the work with Schedule 5 pathogens, toxins and relevant materials are securely controlled. Principal investigators who wish to acquire, possess or use any of these pathogens, toxins or relevant genetic materials must obtain prior permission from their School and ensure that these substances are registered before they are brought into the University. Principal investigators must register their Schedule 5 pathogens and toxins using the RETAIN system. In addition School Biological Safety Advisers must promptly notify the University Biological Safety Adviser in advance by email of the acquisition, possession, use or destruction of any Schedule 5 pathogens, toxins or related materials.

Schools must have a detailed security plan in place and it must be regularly reviewed to ensure it is effective and up to date. There must be security controls for work involving Schedule 5 pathogens and toxins including site, building and laboratory security and robust controls for acquisition, information, storage, use and destruction. An inventory of all relevant materials and authorised users must be supplied on request to the Police. All Schedule 5 materials must be kept securely locked, access must be restricted to authorised users only and detailed records must be kept. Please contact your School Biological Safety Adviser for advice about the specific controls required for any work with these substances. The University Biological Safety Adviser will provide advice on controls as required. If Schools receive any unusual requests or enquiries from any sources about Schedule 5 substances then these must be referred to the Head of School before any information is provided.

The possession or use of any Schedule 5 pathogen, toxin or relevant genetic material is subject to notification to Police Scotland. Schools must provide prior notification to Police Scotland / NaCTSO of designated materials well in advance of possession or use. The Health and Safety Department provides advice on biosecurity and notifications and is the primary point of contact for corporate matters for the Police CTSA and DFT Transport Security Inspectors. The Police CTSA provides practical guidance on the security controls required to Schools and the University. The Department for Transport has additional security requirements for the transport of dangerous goods. Transport Security Inspectors provide practical guidance on the security controls required to the University primarily in relation to the transport of high consequence dangerous goods which includes the most hazardous pathogens and toxins. Schools and principal investigators must comply with NaCTSO / Protect



UK guidance and any instructions given by the Police CTSA and Transport Security Inspectors.

The Police CTSA periodically visits the University to provide advice and conduct inspections of sites, buildings and laboratories which hold Schedule 5 pathogens or toxins to ensure that the possession and use of these materials is in compliance with the law. The police may want to meet managers and principal investigators and they have powers to give direction on security measures. The police are entitled to request and obtain full details of all the security arrangements and controls for the materials which may include full details of persons who have access to these materials, the locations of materials, quantities held, their use, storage; inactivation, waste disposal, and transmission of materials to other persons. Transport Security Inspectors periodically visit the University to provide advice and conduct inspections to ensure that the transport of these dangerous substances is in compliance with the law.

4. Guidance Sources for Biological Security

There is detailed regulatory guidance and information on biological security which is available from the Police, National Counter Terrorism Security Office, Protect UK, National Protective Security Authority and Department for Transport. Please see the links below to some important resources.

4.1 Guidance

- Protect UK (NaCTSO)
- DFT Transporting Dangerous Goods
- DFT Transport Security

4.2 Websites

- Protect UK National Counter Terrorism Security Office
- <u>National Protective Security Authority</u>

Please contact your School Biological Safety Adviser for information and advice before acquiring any materials if you have any questions or are not sure what is required. School Biological Safety Adviser can take advice where needed from the University Biological Safety Adviser and Police CTSA.

5. Schedule 5 List of Pathogens and Toxins

The current Schedule 5 list of materials falls into three broad categories: microorganisms, toxins and genetic sequences.



Viruses

- Chikungunya virus
- Congo-Crimean haemorrhagic fever virus
- Dengue fever virus
- Dobrava / Belgrade virus
- Eastern equine encephalitis virus
- Ebola virus
- Everglades virus
- Getah virus
- Guanarito virus
- Hantaan virus
- Hendra virus (Equine morbillivirus)
- Herpes simiae (B virus)
- Influenza viruses (pandemic strains)
- Japanese encephalitis virus
- Junin virus
- Kyasanur Forest virus
- Lassa fever virus
- Louping ill virus
- Lymphocytic choriomeningitis virus
- Machupo virus
- Marburg virus
- Mayaro virus
- Middleburg virus
- Mobala virus
- Monkey pox virus
- Mucambo virus
- Murray Valley encephalitis virus
- Ndumu virus
- Nipah virus
- Omsk haemorrhagic fever virus
- Polio virus
- Powassan virus
- Rabies virus
- Rift Valley fever virus
- Rocio virus
- Sabia virus
- Sagiyama virus
- SARS Coronavirus
- Sin Nombre virus
- St Louis encephalitis virus
- Tick-borne encephalitis virus (Far eastern encephalitis, formerly Russian Spring summer encephalitis virus)



- Variola virus
- Venezuelan equine encephalitis virus
- Western equine encephalitis virus
- West Nile fever virus
- Yellow fever virus

Rickettsiae

- Coxiella burnetii
- Rickettsia prowazeki
- Rickettsia rickettsii
- Rickettsia typhi (mooseri)

Bacteria

- Bacillus anthracis
- Brucella abortus
- Brucella canis
- Brucella melitensis
- Brucella suis
- Burkholderia mallei (Pseudomonas mallei)
- Burkholderia pseudomallei (Pseudomonas pseudomallei)
- Chlamydophila psittaci
- Clostridium botulinum
- Enterohaemorrhagic Escherichia coli serotype 0157 and verotoxin producing strains
- Francisella tularensis
- Multiple-drug resistant Salmonella paratyphi
- Mycoplasma mycoides mycoides (Contageous bovine pleuropneumonia)
- Salmonella paratyphi A, B, C
- Salmonella typhi
- Shigella boydii
- Shigella dysenteriae
- Shigella flexneri
- Vibrio cholerae
- Yersinia pestis

Toxins

- Abrin
- Botulinum toxins
- Clostridium perfringens epsilon toxin
- Clostridium perfringens enterotoxin
- Conotoxin

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- Modeccin toxin
- Ricin
- Saxitoxin
- Shiga and shiga-like toxins
- Staphylococcal enterotoxins
- Tetrodotoxin
- Viscum Album Lectin 1 (Viscumin)
- Volkensin toxin

Notes

1. Any reference in this Schedule to a microorganism includes:

(a) Intact microorganisms.

(b) Microorganisms which have been genetically modified by any means, but retain the ability to cause serious harm to human health.

(c) Any nucleic acid deriving from a microorganism listed in this Schedule (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious or replication competent forms of any of the listed microorganisms.

(d) Any nucleic acid sequence derived from the microorganism which when inserted into any other living organism alters or enhances that organism's ability to cause serious harm to human health.

- 2. Any reference in this Schedule to a toxin includes:
- (a) Any nucleic acid sequence coding for the toxin.
- (b) Any genetically modified microorganism containing any such sequence.

3. Any reference in this Schedule to a toxin excludes any non-toxigenic subunit.

Animal Pathogens

- African horse sickness virus
- African swine fever virus
- Bluetongue virus
- Classical swine fever virus
- Foot and mouth disease virus
- Goat pox virus
- Hendra virus (Equine morbillivirus)



- Highly pathogenic avian influenza (HPAI) as defined in Annex I(2) of Council Directive 005/94/EC
- Lumpy skin disease virus
- Mycoplasma mycoides mycoides (Contageous bovine pleuropneumonia)
- Newcastle disease virus
- Peste des petits ruminants virus
- Rift Valley fever virus
- Rabies and rabies-related Lyssaviruses
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus

Notes

Any reference in this Schedule to a microorganism includes:

(a) Intact microorganisms.

(b) Microorganisms which have been genetically modified by any means, but retain the ability to cause serious harm to animal health.

(c) Any nucleic acid derived from a microorganism listed in this Schedule (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious or replication competent forms of any of the listed microorganisms.

(d) Any nucleic acid sequence derived from the microorganism which when inserted into any other living organism alters or enhances that organism's ability to cause serious harm to animal health.

Extremely small quantities of some of the above toxins do not have to be notified to the police. Less than 5mg total within a single secure area does not need to be notified. This lower limit does not apply to Clostridium botulinum and Clostridium perfringens (except alpha toxin) toxins. Please note that all pathogens and toxins in Schedule 5 must be registered using RETAIN irrespective of the quantity.

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V1.0	New template	June 2023 HE
V1.1	Minor updates to text and links.	January 2024 PW

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