

Pathogen and Toxin Registration

1. Introduction

The possession or use of biological agents which are pathogens, pathogen infected materials and certain toxins is controlled under health and safety, animal health, plant health, environmental and terrorism legislation. These pathogens and toxins are therefore required to be registered with your School and the University which should be done using the RETAIN online registration system before they are brought into the University. The purpose of this registration process is to ensure that Schools and the University complies with legal requirements for work with these pathogens and toxins by maintaining a complete list of these pathogens, pathogen infected materials and toxins.

2. RETAIN Registration System for Pathogens and Toxins

Pathogens and toxins must be registered using the RETAIN online registration system well before they are obtained or brought into the university.

RETAIN

Principal Investigators or people of similar authority are responsible for pathogen and toxins registration. The registration requirement is exactly the same irrespective of whether the materials are pathogens, toxins, or pathogen or toxin infected materials. The guidance will help you to understand what materials do or do not need to be registered. Please check the relevant guidance and contact your School Biological Safety Adviser for information and advice and if you have any questions or are not sure about what is required before acquiring any materials.

3. Registration of Pathogens and Toxins

You need to register the basic details of pathogens, pathogen infected materials or toxins and not the specific details of every strain or sample that you have or intend to bring into the University although you should provide additional details relating to any unusually virulent or novel strains. The purpose of registration is just to ensure that we maintain a list of pathogens and toxins in Schools and the University and not a list of all individual samples or their movement into and out of the University. This will enable any necessary advice about safety and security controls to be provided to principal investigators by your School Biological Safety Adviser.

You will be asked to provide some basic information for the registration form including the name and email of the principal investigator who is the responsible person, School, name and details of pathogens, pathogen infected materials or toxins, where they are to be obtained, where they are to be kept, whether they are also genetically modified microorganisms or larger genetically modified organisms, and whether they are subject to an animal health licence or plant health licence. The

officially designated names of pathogens and toxins found in the regulatory guidance is used but you should be aware that occasionally the scientific names may be different in current microbial taxonomy. You need to separately register each pathogen or toxin on RETAIN. Different strains of the same pathogen should be put on the same form unless they are a different hazard group. You may be required by your School to register additional information on the RETAIN system.

The RETAIN system database maintains all the registered information for Schools and the University. In addition to registration, Schools and principal investigators also need to keep any relevant records of the pathogens and toxins. The records must be kept readily available for inspection and use in an emergency. Please update your records on RETAIN when you have finished working with your registered material and it has been safely disposed, when you leave the university and take your materials with you, or if you leave the university and leave your materials under another researcher's responsibility.

3.1 Register These Pathogens and Toxins

You must register any pathogens or pathogen infected materials including those classified under the Control of Substances Hazardous to Health Regulations (COSHH), Specified Animal Pathogens (Scotland) Order (SAPO) or Plant Health (Scotland) Orders. You must also register any pathogen, toxin or relevant genetic material listed in Schedule 5 of the Anti-Terrorism, Crime and Security Act (ACTSA).

- Any pathogens classified in group 2 or 3.
- Human pathogens classified in group 2 or 3 under COSHH.
- Animal pathogens classified in group 2 or 3 under SAPO and require an animal health licence.
- Plant pathogens or pests classified under PHO and require a plant health licence
- Human, animal or plant samples or materials known or are likely to contain or be infected with any of the above pathogens.
- Pathogens or relevant genetic materials classified in Schedule 5 of ATCSA.
- Toxins or relevant genetic materials classified in Schedule 5 of ATCSA.
- Biological toxins.
- You must also register any pathogens or pests not appearing in any of the relevant lists when there are reasonable grounds for suspecting it might be a previously unrecognised human, animal or plant pathogen or pest.

3.2 Do Not Register These Pathogens and Toxins

Do not register most of the standard biological or clinical materials or samples that may or may not be contaminated with incidental pathogens or toxins unless there is a known, likely or suspected risk of their presence in the materials.



4. Lists of Regulated Pathogens and Toxins

You can find the details of pathogens and toxins in regulatory guidance and by contacting regulators. Details of human pathogens can be found on the HSE Biological Agents website. Details of animal pathogens which require a SAPO licence can be found on the HSE Animal Health SAPO website. Details of plant pathogens and pests which require a PHO licence can be found on the Plant Health SASA website. Details of Schedule 5 pathogens and toxins can be found on the NaCTSO website.

4.1 Human Pathogens

Human pathogens are classified under the Control of Substances Hazardous to Health Regulations (COSHH) and are listed in the HSE ACDP Approved list of biological agents. Full details can be found on the HSE Biological Agents website.

Human Pathogens

4.2 Serious Animal Pathogens

Serious animal pathogens are classified under the Specified Animal Pathogens (Scotland) Order (SAPO) and are listed in the HSE Containment and control of specified animal pathogens. Full details can be found on the HSE Specified Animal Pathogens website.

Specified Animal Pathogens

4.3 Serious Plant Pathogens and Pests

Serious plant pathogens and pests are classified under the Plant Health (Scotland) Orders and are listed in the relevant orders and unfortunately are not available in a single guidance list. Full details can be found on the Plant Health Scientific Advice for Scottish Agriculture (SASA) website.

Plant Pathogens and Pests

4.4 Schedule 5 Pathogens and Toxins

Details of pathogens and toxins are classified under the Anti-Terrorism, Crime and Security Act (ACTSA) and listed in Schedule 5. Full details can be found on the National Counter Terrorism Office (NaCTSO) website and on the Biological Security section of this website.

ACTSA Schedule 5 Pathogens and Toxins

If you are uncertain of whether any pathogen or toxin or material which might contain pathogens or toxins is controlled or should be registered then you should contact your School Biological Safety Adviser.

5. Guidance Sources for Pathogens and Toxins

There is a lot of very useful guidance and information on pathogens and toxins available from the Health and Safety Executive (HSE), Animal Health or Plant Health and other national and international agencies. Please see the links below to some of the key regulatory guidance and website resources.

5.1 Guidance

- HSE ACDP Approved list of biological agents
- HSE Containment and control of specified animal pathogens
- SASA Plant health licensing
- Animal and Plant Health Agency

5.2 Websites

- HSE Biological Safety
- HSE Biological Agents
- HSE Specified Animal Pathogens
- Animal and Plant Health Agency
- Animal Health (Scotland)
- Plant Health (Scotland)
- Animal Health (England)
- Plant Health (England)
- Public Health (Scotland)
- Public Health (UK Health Security Agency)
- World Health Organization Biological Safety
- World Organisation for Animal Health

Please read the important guidance and information about work with pathogens and toxins and the regulatory and University requirements which is available on the Biosafety Unit website.

Document version

Version number	Summary of change	Date and by whom
V2.0	New template	June 2023 HE
V.2.1	Minor updates to text and links.	January 2024

If you require this document in an alternative format please contact The Health and Safety Department on health.safety@ed.ac.uk or call (0131) 651 4255