Notifications and licensing that may be required when working with biological material. Any communications with statutory agencies must be carried out either by, or with advice from, the University Biological Safety Manager.

U.K. Regulation or Legislation	Enforcing Agency	Main (Permits / Licensing / Notifications) Requirements	Comments
Control of Substances Hazardous to Health Regulations	HSE	If you are working with human pathogens then the HSE must be notified were there is: • Use of any of the following biological agents specifically listed in COSHH (Part V; Schedule 3), Hazard Group 3 or 4 biological agents as well as the following Hazard Group 2 agents: o *Bordetella pertussis* o *Corynebacterium diphtheriae* o *Neisseria meningitides* • Consignment of biological agents in Hazard Group 4 to or from a premise.	Health and Safety requirements are addressed in the hazardous biological materials standard. Form CBA1 must be completed and returned via University Biological Safety Manager to the HSE at least 20 days before any new work begins. If any GM work is also involved in a project then notification should be through the GM route only (see below).
Genetically Modified Organisms (Contained Use) Regulations	HSE	If you want to work with GMOs in containment the HSE must be notified were there is: • Any new projects using GM organisms from Hazard Group 2, 3, or 4. • Any accidents involving GM organisms (includes significant and unintended releases, harm to individuals etc.). • Any transfers of projects from one organisation to another. • Any extension of the site licence to another location.	Health and Safety requirements are addressed in the hazardous biological materials standard. Complete and submit the relevant HSE form via University Biological Safety Manager: HSE form CU2 for new projects HSE form CU3 for accidents HSE form CU4 for transfer of projects. **For new projects or significant modifications to an existing project a payment to the HSE is required.**
Specified Animal Pathogens Order	DEFRA HSE LA	You must have a licence from DEFRA if you wish to: • possess any animal pathogen specified in Part 1 of Schedule 1 to the Specified Animal Pathogens Order including pathogens which have been modified or any nucleic acid derived from a specified animal pathogen that is capable of producing that pathogen, • possess any carrier in which you know a specified pathogen is present, • introduce into any animal, including poultry, any animal pathogen specified in either Part 1 or Part 2 of that Schedule.	Health and Safety requirements are addressed in the hazardous biological materials standard. Currently licensing under the order is processed by DEFRA, and enforcement is carried out by the HSE. If you possess anything which you suspect may contain a specified animal pathogen and you do not have the appropriate licence, you must immediately notify DEFRA via the University Biological Safety Manager

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Anti-terrorism, Crime and Security Act 2001	Home Office & Police	If you provide laboratory services and you hold any of the pathogens and toxins listed in Schedule 5 of the Anti-Terrorism Crime and Security Act 2001 you must notify the Home Office.	The Home Office will arrange, via the National Counter Terrorism Security Office (NaCTSO), a site visit by the relevant Counter Terrorism Security Advisor (CTSA) to conduct a survey and provide commensurate security advice and guidance. Qualifying sites must be able to demonstrate to the CTSA that they are operating securely before they are granted authority by NaCTSO on behalf of the Home Office.
Chemical Weapons Act	DECC	Under the Chemical Weapons Convention (CWC), a state party must submit detailed annual declarations on particular activities involving certain chemicals, and these declarations are subject to verification by OPCW inspectors. The UK's export and import licensing procedures control the trade in those chemicals covered by the CWC. The hazardous biological materials covered by the convention are saxitoxin and ricin.	The Chemical Weapons Convention (CWC) entered into force on 29 April 1997, and is the first arms-control treaty that works to introduce a verifiable ban on an entire class of weapons of mass destruction. It is administered by the Organisation for the Prohibition of Chemical Weapons (OPCW), which is based in The Hague. DECC, as the UK CWC National Authority, is responsible for implementing the CWC throughout the UK, the Crown Dependencies and the Overseas Territories. The powers to do this are contained in the Chemical Weapons Act 1996.
Various Carriage of Dangerous Goods Regulations	HSE VOSA HMRC CAA	If you consign goods that are classified as potentially dangerous when transported, you must arrange their packing and transportation by air, sea, road, rail or inland waterway according to international regulations. The United Nations (UN) Model Regulations harmonise the rules on the various methods of transportation.	Hazardous biological material (including genetically modified organisms and pathogens of humans and animals) fall into UN hazard classes 6.2 (infectious material) or 9 (miscellaneous). When transported by public means (road/rail/air/water) hazardous materials must be packed in accordance with UN packing requirements.
Genetically Modified Organisms (Deliberate Release) Regulations	DEFRA	If you wish to market or release genetically modified organisms (GMOs) into the environment, you must gain permission before you do so. There are two kinds of 'release' covered by the legislation: • Part B release covers non-commercial use of GMOs, such as use in research trials. • Part C release covers the commercial use of GMOs.	If you wish to carry out research trials in England, you must apply to the Department for Environment, Food and Rural Affairs (DEFRA). You must include an environmental risk assessment as part of the application. Applications to market a GMO in the European Union (EU) can be made to any Member State's Competent Authority. If the initial application is made in the UK, DEFRA will consult with other EU member states before a collective EU decision is made on whether to grant permission. Applications for products for food and feed will require approval under the GMO Food and Feed Regulations.

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The Genetically Modified Organisms (Trans-boundary Movements) (England) Regulations	LA HSE	If you export genetically modified organisms (GMOs) outside the European Union (EU) you must ensure that you have authorisation from the competent authority of the country you are exporting to.	Your local authority or the Health & Safety Executive may inspect your premises to ensure you are complying.
The Medicines for Human Use (Marketing Authorisations Etc.) Regulations	MHRA	If you manufacture medicinal products for sale in the UK or sell them wholesale, you must obtain marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) or an equivalent body in another European state. You must satisfy the MHRA that your product is safe for public use.	Each product is categorised as either: • prescription only • sale only from a pharmacy • general sale You must also comply with rules on: • giving specified and updated information to the MHRA about your products • making changes when required • pharmacovigilance • labels and package leaflets In cases of emergency, the MHRA can impose restrictions, e.g. withdrawal from public sales.
Medicine for Human Use (Clinical Trials) Regulations	MHRA	The Medicines for Human Use (Clinical Trials) Regulations 2004 control how research undertaken to ascertain the safety or efficacy of a medicinal product in human participants should be conducted. See the MHRA website for further details	Most of the legal requirements were already part of current UK clinical trials practice. However, new controls include: • Each clinical trial must have an identified sponsor who takes responsibility for its initiation and management • Pharmacology studies in healthy human volunteers (Phase 1) must be authorised by MHRA • Ethics Committee system established on a statutory basis • Specific timescales for ethics review • Investigational medicinal products (IMPs) must be manufactured only at licensed manufacturing sites to good manufacturing practice (GMP) standards • Additional protection for incapacitated adults and minors in clinical trials • MHRA inspections of clinical trials must be facilitated It is also now a legal obligation to conduct clinical trials of medicinal products in accordance with principles on good clinical practice (GCP)

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Human Fertilisation and Embryology Act	HFEA	To undertake the procurement, testing, processing, preservation, storage and distribution of eggs, sperm, embryos and/or to provide in-vitro fertilisation, or artificial insemination treatments, you need to register for a licence with the Human Fertilisation and Embryology Authority (HFEA).	The Act also requires the HFEA keep a database of every IVF treatment carried out since that date and a database relating to all cycles and use of donated gametes (egg and sperm).
Good Laboratory Practice Regulations	GLPMA	The GLP Regulations and the Guide apply to any test facility which conducts, or intends to conduct, a regulatory study.	A regulatory study is a study for which the regulatory authority to whom the data will be submitted, requires that study to be conducted in compliance with the principles of GLP.
Importation of Animal Pathogens Order	DEFRA HMRC	If you import animal pathogens (e.g. virus or bacteria or yeast) or carriers (e.g. mites, ticks, fleas etc.) from countries outside the EU, you'll need a special licence.	HMRC will notify DEFRA if there are any border control infringements. Licences will not be issued for importations of pathogens or their carriers by post.
Importation of Animal Products and Poultry Products Order	DEFRA	No live animal or animal product may be brought in to England from a third county except via a border inspection post (BIP).	If you import animals, you must notify the BIP at least one working day before its arrival. If you import animal products, you must notify the BIP before it is unloaded from its transport. Notification must be made by submitting the Common Veterinary Entry Document (CVED) with Part 1 completed. The consignment will be inspected by the local authority or the Animal Health and Veterinary Laboratories Agency (AHVLA) who will complete Part 2 of the CVED if: • all requirements are met • the importation isn't prohibited • the correct fee has been paid
Export Control Act	ECO	Any item exported from the UK that is subject to export control needs a licence	The Export Control Organisation is responsible for assessing and issuing (or refusing) export licences for a wide range of controlled “strategic” goods. This includes military and dual-use items, see the Strategic Export Control Lists for further details

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The Rabies (Importation of Dogs, Cats and Other Mammals) Order	DEFRA MCA CAA	All Rabies susceptible animals entering the United Kingdom are subject to controls to prevent the potential importation of Rabies and certain other animal diseases. Susceptible animals that do not qualify for entry into the UK under the current Pet Travel Scheme and are required by law to spend 6 months in quarantine.	If you are bringing an animal into rabies quarantine in the UK, you must be issued with an import licence.
Animal Health Act	LA	This Act regulates the prevention, control and eradication of animal diseases. It provides emergency powers to respond to the outbreak of exotic diseases and covers aspects of disease control, including the following: • eradication and prevention of disease • dealing with an outbreak of disease • powers of entry - for veterinary inspectors • seizure of infected animals • slaughter and compensation • disposal of infected carcases • cleansing and movement of animals, personnel and vehicles • empowerment of local authorities and enforcement	Certain diseases are classified as notifiable. If you suspect an animal has a notifiable disease you must inform your Animal Health Office (AHO) immediately.
Veterinary Medicines Regulations	VMD	Under this regulation it is an offence to give any veterinary medicine to livestock animals unless those medicines have a marketing authorisation for their use in the UK.	Contact the VMD for varying and renewing specific authorisations including Marketing Authorisations, Registered homeopathic remedies, Animal Test Certificates, and Authorisations for specific manufacturers, i.e. autogenous vaccines, non-food animal blood banks and equine stem cell centres.
Animals (Scientific Procedures) Act	Home Office	If you undertake any experimental or other scientific procedures on a protected animal which may have the effect of causing that animal pain, suffering, distress or lasting harm, you must first obtain a licence from the Home Office.	Two kinds of licence are required for all work controlled by the Act. The procedures must be part of a programme of work authorised by a project licence and the person applying the regulated procedures must hold a personal licence. No work may be done unless the procedure, the animals used and the place where the work is to be done are specifically authorised in both project and personal licences

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Dangerous Wild Animals Act	DEFRA LA	If you intend to keep dangerous wild animals, other than in a zoo or pet shop, you must apply to your local authority for a licence to do so. Licences are required for specific animals and you can check which these are with the Department for Environment, Food and Rural Affairs.	Licences will be granted when the authority is satisfied that: • keeping the animal would not cause a threat to the public • the animal's accommodation is safe and adequate • the animal is supplied with adequate food, drink and bedding material • the animal will not be moved from licensed premises • you have insurance against any damage or injury caused by the animal • the applicant is a suitable person
Pests Act	DEFRA	If wild rabbits live on your land you must control them or take steps - such as using fencing - to prevent them causing damage. If you wish to trap and destroy wild rabbits or other animals, you may only use approved spring traps. You cannot use rabbits with myxomatosis to spread the disease among uninfected rabbits.	Under Section 12 of the Pests Act 1954, it is an offence to knowingly spread myxomatosis to uninfected rabbits. This prohibition means that the deliberate spreading of myxomatosis cannot be used as a legal method of controlling rabbits. Work with the myxomatosis virus (as well as Viral Hemorrhagic Disease of Rabbits) will be governed by this Act.
Fish Health Regulations	CEFAS	The Centre for Environment Fisheries and Aquaculture Science is an executive agency of DEFRA. It regulates the fish and shellfish farming industries and licenses and monitors imports and exports of live fish and shellfish	The governments Aquatic Animal Health and Movements website, explains what you need to do to export and import live fish, shellfish and crustacea in England and Wales. It also has information on keeping and releasing non-native species.
Diseases of Fish (Control) Regulations	CEFAS	This regulation enacts EU Council Directive 2006/88/EC and sets out legislation to prevent and control certain diseases in aquatic animals. These diseases are 'notifiable' - i.e. the owner or anyone else attending to the animals must immediately report suspicion of notifiable diseases to the Fish Health Inspectorate (one of CEFAS specialist units).	Where a notifiable disease is suspected in aquatic animals (fish, molluscs or crustaceans), the Fish Health Inspectorate (FHI) will undertake an investigation and samples will be taken for diagnostic testing. The FHI will also apply controls to the affected area in the form of an initial designation notice in order to minimise the risk of any further disease spreading.
The Bees Act	FERA	The Act seeks to stop the damage caused by diseases, chemicals and pests that harm bees.	The Act empowers Ministers or the Secretary of State to make Orders to control pests and diseases affecting bees, and provides powers of entry for Authorised persons. The FERA National Bee Unit is responsible for apiary surveillance and pests and disease control in England and Wales. See BeeBase for more information

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Plant Health Order (England / Scotland / Northern Ireland)	FERA	Plant health legislation controls the import and movement of certain plants, seeds and organic matter - such as soil - and certain plant products, including fruit, potatoes, vegetables, cut flowers, foliage and grain from outside the European Union.	Controls differ according to the species - and whether or not they are classified as quarantine organisms - but could include the need for classification, a phytosanitary certificate, a plant passport and/or inspection requirements. The Food and Environment Research Agency's (FERA's) Plant Health Division is responsible for plant health policy. The Plant Health and Seeds Inspectorate (PHSI) is part of FERA and implements and enforces plant health policy. If you want to grow, import, export or move certain plants or plant material, you will need to use the PHSI's services. protection against quarantine organisms - measures to prevent the introduction and spread of harmful plant pests and diseases which are not established in the European Union
Plant Health (Forestry) Order	Forestry Commission	If you are importing wood or wood products and other relevant material from non European Community countries you must: • register as an importer with the Forestry Commission • provide advance notification of consignments landing • produce any necessary documentation to an inspector at the time of landing	The Order is the principal instrument in Great Britain implementing the plant health requirements in the European Community for forestry material, set out in Council Directive 2000/29/EC

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Wildlife and Countryside Act	Natural England	If your business affects or involves wildlife you must not, unless you are licensed to do so (or you can rely on an exception or are shooting certain lists birds outside the close season), intentionally: • kill, injure or take any wild bird • take, damage or destroy any wild bird's nest while it is being used or built • take or destroy the eggs of any wild bird If you are within an area designated for special protection by Defra, you must comply with special bird protection rules for that area. You must not sell or advertise wild birds or wild bird eggs unless you are licensed. You must register any bird listed on Schedule 4 with Animal Health. You must not, unless you are licensed, intentionally or recklessly: • kill, injure, take, or trade in any wild animal listed on Schedule 5 • damage or destroy or obstruct access to any structure or place used by a wild animal listed on Schedule 5, or disturb such an animal while it is occupying such a shelter or place • disturb a sea mammal Unless you are licensed to do so, you must not kill or take wild birds or animals You must not pick, uproot, destroy, trade in or possess (for the purposes of trade) any wild plant listed on Schedule 8, unless you are licensed, or uproot any wild plant unless you are authorised. You may apply for licences from Natural England for various purposes including: • scientific research • conservation • re-populating species • animal protection • photography • taxidermy • preventing serious damage to agriculture or inland waters If you farm, trap or otherwise deal in animals or plants, you must not: • release or allow to escape into the wild any animal that is not ordinarily resident in Great Britain, or is listed on Schedule 9 • plant or otherwise cause to grow in the wild any plant that is listed on Schedule 9	
The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)	DEFRA HMRC Police	The import, export and use for commercial gain of certain species requires a CITES permit. DEFRAs Animal Health's wildlife licensing and registration service is the part of the UK CITES management authority responsible for dealing with CITES applications.	H.M. Revenue & Customs are responsible under the Customs and Excise Management Acts for the enforcement of CITES controls on trade between the UK and non-EC states, but enforcement within the UK is the responsibility of the police.

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Conservation (Natural Habitats &c.) Regulations	Natural England	This regulation transposes Council Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora (EC Habitats Directive) into national law.	Containing five Parts and four Schedules, the Regulations provide for the designation and protection of 'European sites', the protection of 'European protected species', and the adaptation of planning and other controls for the protection of European Sites.
Convention on Biological Diversity	Natural England	The Convention on Biological Diversity (CBD) is the first global agreement to cover all aspects of biological diversity including genetic resources, species and ecosystems. It is also the first to recognize that the conservation of biological diversity is 'a common concern of humankind' and an integral part of sustainable development. Because of this worldwide concern, over 150 countries, including the UK, signed the Convention on Biological Diversity at Rio de Janeiro, South America in 1992.	The CBD has three main objectives: • the conservation of biodiversity; • the sustainable use of biodiversity; and • the sharing of benefits from the use of genetic resources (including by appropriate access to these resources).
The Offshore Marine Conservation (Natural Habitats, &c.) Regulations	Marine Management Organisation	A wildlife licence is required by anyone who wishes to carry out an activity in the English marine environment or the Welsh offshore environment that is prohibited under nature conservation legislation, where the activity cannot be sufficiently mitigated against. For example, a licence to disturb certain species during construction of wind farms or a licence to carry out scientific surveys.	An applicant will need to provide details on the activity they wish to carry out, what species will be affected and for what purpose they wish to apply for a licence.
Environmental Protection Act	EA	You have a legal responsibility for the impact your activities has on the environment. For example, it's up to you to ensure that your waste is treated and disposed of properly.	Business activities that may cause pollution or that pose another risk to the environment are regulated. You must ensure that you have appropriate authorisation for your activities. Some types of permit are issued by the Environment Agency, others by your local authority or water and sewerage company. The main environmental authorisations include environmental permits and exemptions, trade effluent consents and agreements for discharges to public foul sewers, water abstraction and impoundment licences and hazardous waste registration.
Highways Act	Highways Agency	The Act provides highway authorities with powers to approve planting by others within the highway.	Under Section 142 of the Highways Act 1980, a licence must be applied for and granted before anything can be planted along the highway. A licence can only be granted to the adjacent land owner.

Centre for Environment Fisheries and Aquaculture Science

Civil Aviation Authority

Department for Environment, Food and Rural Affairs

Department of Energy and Climate Change

Environment Agency

Export Control Organisation

Food and Environment Research Agency

Good Laboratory Practice Monitoring Authority

Health & Safety Executive

HM Revenue & Customs or Business Link (government's online resource for business)

Human Fertilisation and Embryology Authority

Local Authority

Medicines and Healthcare products Regulatory Agency

Vehicle and Operator Services Agency or Business Link (the government's online resource for business)

Veterinary Medicines Directorate