

UNITED KINGDOM (ONLY MEASURES PERTAINING TO BIOLOGY)

Penal Measures

The United Kingdom's penal legislation for crimes involving biological weapons consists of two acts: The Biological Weapons Act 1974 and The Anti-Terrorism, Crime and Security Act 2001. The Biological Weapons Act 1974 (BWA) implements the provisions of the 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction. Section 1 of the BWA mandates that:

No person shall develop, produce, stockpile, acquire or retain-

- (a) any biological agent or toxin of a type and in a quantity that has no justification for prophylactic, protective or other peaceful purposes; or
- (b) any weapon, equipment or means of delivery designed to use biological agents or toxins for hostile purposes or in armed conflict.

Under the act, a person guilty of the above offense may be imprisoned for life. The remainder of the act specifies that the Act is applicable to corporate bodies and authorizes the grants of search warrants for the investigation of violations of the Act.

The Anti-Terrorism, Crime and Security Act 2001 (ATCSA) was implemented after the September 11, 2001 terrorists attacks on the United States. ATCSA amends the BWA to include the following prohibition: A person shall not-

- (a) transfer any biological agent or toxin to another person or enter into an agreement to do so, or
- (b) make arrangements under which another person transfers any biological agent or toxin or enters into an agreement with a third person to do so,

if the biological agent or toxin is likely to be kept or used (whether by the transferee or any other person) otherwise than for prophylactic, protective or other peaceful purposes and he knows or has reason to believe that that is the case.

The ATCSA also contains provisions to create extraterritorial jurisdiction over violations of Section 1 of the BWA, but only when they are done by a United Kingdom person.

Commissioners of Customs and Excise can institute proceedings if it appears that an offense has involved development or production outside the United Kingdom of a biological agent, the movement of any such thing into or out of any country or territory or any proposal or attempt to do any of the activities prohibited in Section 1 of the BWA. Under the ATCSA, a person who "aids, abets, counsels or procures, or incites, a person who is not a United Kingdom person do a relevant act [prohibited by Section 1 of the BWA] outside the United Kingdom is guilty of an offence" and may be subject to imprisonment for life upon conviction. "This section applies to acts done outside the United Kingdom, but only if they are done by a United Kingdom person". Proceedings for an offence committed under outside the United Kingdom may be commenced, and the offence may be treated as having been committed, in any part of the United Kingdom.

Regulations of Pathogens

A Ministry of Agriculture Fisheries and Food (MAFF) license is required for obtaining non-indigenous plant pathogens. The shipper is required to see a copy of the Ministry permit before such strains can be supplied. The Animals Pathogens Order 1998 makes it an offense to possess or spread a listed animal pathogen without a license, and the Animal Pathogens Order 1980 makes it an offense to import any animal pathogen, or potential or actual carrier, from a non-EC country without a license. Both the supplier and recipient must hold the appropriate licenses and undergo regular inspections from MAFF. The UK National Culture Collections are implementing a system involving the registration of customers to ensure bona fide supply.

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Under both UK and European legislation, microbiologists must make a risk assessment on the organisms with which they work or hold in collections. The ACDP defines and sets minimum handling procedures of pathogenic organisms grouped into four hazard groups 1-4 with corresponding containment levels.

Microorganisms of hazard groups 2, 3, and 4 are hazardous substances under the UK Control of Substances Hazardous to Health (COSHH) regulations which formalizes, enforces, and extends certain sections of the Health and Safety at Work Act s.6(4)(c) and subject to the Approved Code of Practice for Biological Agents 1994. All facilities handling hazard group 2, 3, or 4 must be registered; strict controls apply to hazard group 3 and 4 organisms. Under these regulations, every employer must assess the risks to health and safety for any person, whether employed by them or not, might face due to exposure to a hazardous substance. Yet, because it may be difficult to assess the risk of a hazard whose full metabolic and biochemical potential is not fully known, the COSHH requirements for setting workable safety procedures include terms which leave room for interpretation: 'as far as reasonably practicable', 'adequate control', and 'suitable measures'.

There are legal requirements under the Management of Health and Safety at Work Regulations 1999 (MHSR), which cover the supervision of workers and the monitoring of standards. They state that arrangements must be made for the effective planning, organization, control and monitoring of preventive and protective measures. Biological Safety Officers are to be established to ensure that adequate containment facilities and procedures are in place to control any risks to workers and the environment; to maintain and test equipment at appropriate intervals and where necessary to monitor for the presence of viable process organisms outside of containment; to provide adequate training commensurate with the level of risk; to formulate and implement local rules; to formulate and implement emergency plans and procedures

There are also obligations on managers of laboratories that hold stocks of specified disease-causing micro-organisms and toxins to notify their holdings, and to comply with any security requirements which the police may impose. A safety data sheet must be dispatched with an organism indicating which hazard group it belongs to and what containment and disposal procedures are necessary. Managers of laboratories and other premises must also furnish to the police details of people with access to the dangerous substances held there. The Secretary of State is given power to direct that a named individual must not be allowed access to such disease strains or the premises in which they are held.

Detailed national transport guidelines require that domestic transport of pathogens is performed under optimum conditions for the personal safety and protection of property and the environment. Carriage by rail or road is covered by the Classification, Packaging and Labeling of Dangerous Goods for Carriage by Road or Rail Regulations. Transport by air must comply with the International Air Transport Association (IATA) Restricted Articles Regulations, including a Shipper's Certificate for Restricted Articles, which requires content, nature and quantity of infectious material to be disclosed.

Regulation of Genetically Modified Organisms

Genetically modified organisms (GMS's) are separately regulated by the Advisory Committee on Genetic Manipulation (ACGM). GMS's also require Containment Level 2 for handling, and all potential work with such organisms must first be referred to the place of work's Biological Safety Officer and Biological Safety Committee. The Genetically Modified Organisms(Contained Use) Regulations 2000 replace the prior 1992 regulations and their amendments. The regulations mandate that any activity involving genetic modification of organisms is prohibited unless there has been an assessment of the risks created by that activity to human health and the environment has been carried out. A person who carries out such an assessment is required to establish a safety committee.

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Before a premises can be used for the first time for any activity involving genetic modification, the competent authority must be notified (the competent authority varies by region). The regulations prohibit the undertaking of certain types of activity involving the genetic modification unless the competent authority has been given prior notification together with certain information and, in specified circumstances, the competent authority has given its consent. The regulations impose on a person who undertakes an activity involving genetic modification a requirement to ensure that safety principles are observed. A person who undertakes an activity involving genetic modification of micro-organisms is required to apply the containment measures which are appropriate to that activity. In certain circumstances, before a person undertakes an activity involving genetic modification of micro-organisms, he must prepare an emergency plan to secure the health of persons and the protection of the environment. A person who undertakes an activity involving genetic modification of organisms must report to the competent authority every accident and provide that authority with information about the accident. The Regulations contain provisions relating to the confidentiality of information provided to the competent authority.

Regulation of Biological Exports

The United Kingdom has several legislative instruments and regulations restricting the export of dual-use technologies and potentially pathogens. The UK is also bound by European Union regulations restricting the export of certain materials. Additionally, the UK is a party to international organizations which control the export of certain goods, including the Australia Group. The Import, Export and Customs Powers (Defence) Act 1939 provides the Secretary of State with power to impose import and export controls on goods. Although originally drafted as a temporary measure, the 1939 Act has remained in force ever since.

The Export of Goods (Control) Order 1994 (as amended) includes a list of military, security and paramilitary goods and arms, ammunition and related material whose export is controlled. Specifically, this legislation controls “Goods capable of being used in relation to chemical, biological or nuclear weapons and related missiles,” and “Materials, Chemicals, Microorganisms and Toxins.” The Dual-Use and Related Goods (Export Control) Regulations 1996 (as amended) (DUEC), includes a list of Dual-Use Goods whose export is controlled nationally by the UK. Some of these controls apply to all destinations, in certain cases including member states of the EU, others are specific to just a few destinations.

The Export Control Act 2002 includes powers to impose controls on exports from the UK; impose controls on the transfer of technology from the UK and by UK persons anywhere by any means; impose controls on the provision of technical assistance overseas; impose controls on the acquisition, disposal or movement of goods or on activities which facilitate such acquisition, disposal or movement; prescribe licensing procedures in respect of any of the controls imposed; require the Secretary of State to report annually to Parliament on the controls imposed on both strategic and cultural exports under the Act; require the Secretary of State to issue guidance about the general principles to be followed when exercising licensing powers; enable penalties for export control offences to be imposed, increased or varied to reflect the seriousness of the offences.

The UK’s export scheme is based on the issuance of licenses to export strategic goods and policed by the Customs and Excise Department. To export certain infectious agents to members of the Australia Group requires an Open General Export License (OGEL) from the UK Department of Trade and Industry (DTI); only organizations registered with the DTI may so export. Exports of these agents outside the Australia Group require an Individual Export License (IEL) and only individuals nominated by their senior management and who are registered with the DTI may submit an application for an IEL. Failure to comply with these requirements is a criminal offense. Crucially, all the relevant licence applications are circulated to other government departments with policy responsibilities in that area, e.g. Foreign and Commonwealth Office, Ministry of Defence and the Department for International Development.

Oversight of Research

The Department of Trade and Industry controls seven research councils (RCUK), supported by the Director General of the RCUK, within the Office of Science and Technology. A new strategy group, Research Councils UK, was formally launched on 1 May 2002, to enable the Councils to work collectively within the Office of Science and Technology. One of the seven research councils is the Biotechnology and Biological Sciences Research Council (BBSRC). Within the BBSRC are several committees, including the Biochemistry and Cell Biology Committee and the Biomolecular Sciences Committee. BBSRC's purpose is to provide advice on research involving biotechnology or the biological sciences. The Office of Science and Technology provides more general guidance in all areas of research, coordinating and developing policy on how government seeks and uses scientific advice in policy making, the presentation of that advice, and decisions based on it. The Microbiological Research Authority was statutorily established under the Microbiological Research Authority Order 1994. The MRA is composed of a Chairman who is to be appointed by the Secretary of State, not less than five members nor more than ten, the Chief Officer of the Authority and not more than two other members who are officers of the authority.

For research involving DNA, the U.K. has set up the Health and Safety Executive (HSE) under the Health and Safety at Work Act of 1974. It is primarily concerned with the protection of human health from possible ill effects of any workplace activity. Genetic modification and any activities in which genetically modified cells or organisms are cultured, stored, used, transported, destroyed or disposed of, under conditions of containment, are subject to the control of HSE under the Genetically Modified Organisms (Contained Use) Regulations 1992, which are made under HSWA. The Gene Therapy Advisory Committee (GTAC) advises Health Ministers on developments in gene therapy research and their implications. It reviews and may approve individual protocols for gene therapy research. It works closely with the statutory body for medical products, the Medicines Control Agency (MCA), and with research ethics committees.

GTAC's approval must be obtained before somatic gene therapy or gene transfer research is conducted on human subjects. The submission should contain sufficient technical detail to permit GTAC and its expert advisers to conduct an adequate review in the following areas: (1) objectives and rationale of the proposed research; (2) design of the research; (3) conduct of the research; (4) public health considerations; (5) qualifications of the responsible and other principal investigators; and (6) clinical facilities and arrangements. Responsibility for deciding whether a research proposal should proceed within the National Health Service (NHS) lies with the NHS body with whose sphere of responsibility the research should take place. NHS bodies are asked to ensure that the proposal has been submitted to the appropriate Local Research Ethics Committees (LREC) for ethical approval. The LREC must be consulted about any research proposal involving NHS patients.

BIBLIOGRAPHY OF UNITED KINGDOM LEGISLATION

1. UK Control of Substances Hazardous to Health (COSHH) legislation:
2. Management of Health and Safety at Work (MHSW) Regulations 1992
3. Health and Safety at Work Act 1974
4. Biological Weapons Act 1974
5. Anti-terrorism, Crime and Security Act 2001
6. The Export of Goods (Control) Order 1994 No. 1191:
7. The Export of Goods (Control) (Amendment) Order 2001 Statutory Instrument 2001 No. 729
8. The Dual-Use and Related Goods (Export Control) Regulations 1996 Statutory Instrument 1996 No. 2721
9. Statutory Instrument 2000 No. 994
10. The Dual-Use and Related Goods (Export Control) (Amendment) Regulations 2000
11. The Export of Goods (Control) (Amendment No. 2) Order 2001 Statutory Instrument 2001 No. 3166
12. Export Control Act 2002:
13. The Environmental Protection Act 1990 (EPA)
14. The Genetically Modified Organisms(Contained Use) Regulations 2000 Statutory Instrument 2000 No. 2831
15. The Carriage of Dangerous Goods (Classification, Packaging and Labelling) Regulations No. 303, 11 February 1999
16. The Carriage of Dangerous Goods by Rail Regulations No. 2089, 8 August 1996
17. The Carriage of Dangerous Goods and Use of Transportable Pressure Receptacles Regulations No. 2092, 8 August 1996
18. The Carriage of Dangerous Goods by Road No. 2095, 8 August 1996
19. The Genetically Modified Organisms (Deliberate Release) Regulations No. 1900, 30 July 1997
20. The Genetically Modified Organisms (Deliberate Release) Regulations No. 304, 9 February 1995
21. Amends the 1992 regulations.
22. The Genetically Modified Organisms (Deliberate Release) Regulations No. 3280, 21 December 1992
23. Reporting of Injuries, Diseases and Dangerous Occurrences Regulations No. 3136, 6 December 1995
24. Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations No. 2367, 24 September 1997