

BIOSAFETY-EUROPE

**Containment level 3 and 4 laboratories:
Legislative and regulatory framework**



**SIXTH FRAMEWORK
PROGRAMME**

The biosafety and biosecurity legislative/regulatory framework is set out below for selected European countries.

The text contains information on national biosecurity and biosafety legislation. A short description of how the Directive 2000/54/EC (on the protection of workers from risks related to exposure to biological agents at work) and Directives 90/219/EEC and 98/81/EC (on the contained use of genetically modified micro-organisms (GMMs)) are implemented into national regulations are outlined together with the administrative procedures for risk assessment notifications and inspections.

The procedure for implementation of the EU directives provides the member states with a certain degree of flexibility in determining how the objectives for the directives are to be achieved.

Legislation for the following countries is described below:

Austria
Belgium
Germany
France
Ireland
Norway
Sweden
Switzerland
The Netherlands
UK

1. Austria

Biosafety – National Legislation

Work with Biological Agents

Austria is a federal republic divided into nine states (Bundesländer). These states are then divided into districts (Bezirke) and cities (Statutarstädte). The Ordinance on the Protection of Employees against Hazards caused by Biological Agents (Verordnung biologische Arbeitsstoffe –VbA BGBl. II Nr. 237/1998) has been passed by the Minister for Labour, Health and Social Affairs in 1998. It prescribes measures to be taken to avoid risks and dangers for employees resulting from work with biological agents such as equipment, hygiene, handling of agents, reduction of exposure, vaccination of employees etc. An annex contains a classification of organisms.

Contained use of GMM/GMO

[The Federal Ministry for Health, Family and Youth](#) (BMGFJ) is in charge of any aspects concerning genetic engineering in Austria. Further competencies in this area are given to the Ministry for Science and Research and the Ministry for Agriculture and Environment. The Austrian Gene Technology Act regulates the main aspects of biotechnology and genetic engineering, including contained use of genetically modified organisms (GMOs). Directive 98/81/EC was transposed into legislation via amendment of the Gene Technique Law and later implemented by a System Regulation. The Ordinance on Work with GMOs in Contained Use (Systemverordnung 2002 BGBl. Nr.431/2002) regulates details, such as risk assessment, the classification of GMOs, the necessary equipment of laboratories according to classification and scale, qualification of staff, safety aspects and the measures to be taken in case of accidents.

Risk assessment

In Austria, the classification precisely follows the four class system of Article 5 of Directive 98/81/EC. The organisation that notifies an installation is required to appoint an independent Representative and a Committee for Biological Safety to check the safety classification and the safety measures. For activities, equal or greater than Class 2, a Project Leader has to be appointed to take responsibility for planning, guidance and supervision.

Inspections

In Austria, the authorities in charge have carried out spot checks of activities in Classes 1 and 2.

Competent authorities on GMM/GMO

Federal Ministry for Health, Family and Youth ([Bundesministerium für Gesundheit, Familie and Jugend, BMGFJ](#))

<http://www.bmgfj.gv.at/>

2. Belgium

Biosafety – National Legislation

Work with Biological Agents

The federal Belgium government is divided into three regions, Flanders, Walloon and Brussels Capital, each with its own legislative authority. Workplace health and safety, on the other hand, remains the responsibility for the central government and the competent authority on protection of workers against biological agents is the [Federal Public Service Employment, Labour and Social Dialogue](#).

Directive 2000/54/EC is implemented in the Belgium legislation and the law in force is the Royal Decision of April 29, 1999 (Belgian Official Journal of 07.10.1999 - p. 37917) amending the Royal Decision of August 4, 1996 concerning the protection of workers from risks related to exposure to biological agents at work.

Contained use of GMM/GMO

The contained use of (GMOs) and genetically modified micro-organisms (GMMs) or organisms and/or pathogens is regulated in Belgium at the regional level (Flanders, Walloon and Brussels-Capital). Regions are responsible for the follow-up of administrative procedures, for authorisations and for inspections. The scientific evaluation is made in a centralized way by the [Division of Biosafety and Biotechnology](#).

The three Regions have implemented Directives 90/219/EEC and 98/81/EC as part of their Environmental laws for classified installations. In such a general context, biosafety is just one of the safety issues covered by the environmental permit. Although the EU regulatory framework only covers genetically modified micro-organisms, the scope of the Belgian regional legislations has been extended to genetically modified organisms and pathogenic organisms for humans, animals and plants. For full text of the regional regulations see Regulatory framework and procedures in the [Flemish Region](#), [Walloon Region](#) and [Brussels-Capital Region](#).

For more information about the legislation see: Summary report on the experience of Belgium with Directive 90/219/EEC as amended by directive 98/81/EC: [Period 1999 – 2002](#), [Period June 2003 – June 2006](#) (<http://www.biosafety-europe.eu>).

Risk assessment

In Belgium, the risk assessment principles of Annex III to the Directive 98/81/EC have been integrated into national law.

Inspections

Inspections are organized in the three regions on a regular basis. For more information see; Summary report on the experience of Belgium with Directive 90/219/EEC as amended by directive 98/81/EC: [Period 1999 – 2002](#), [Period June 2003 – June 2006](#) (<http://www.biosafety-europe.eu>).

Competent authorities on GMM/GMO

[Competent Authorities in the Flemish Region](http://www.biosafety.be/CU/EN/CACUVGEN.html) <http://www.biosafety.be/CU/EN/CACUVGEN.html>

[Competent Authorities in the Walloon Region <http://www.biosafety.be/CU/EN/CACURWEN.html>](http://www.biosafety.be/CU/EN/CACURWEN.html)

[Competent Authorities in the Brussels Region <http://www.biosafety.be/CU/EN/CACURBEN.html>](http://www.biosafety.be/CU/EN/CACURBEN.html)

[Division of Biosafety and Biotechnology \(SBB\) <http://www.biosafety.be/GB/AdressesGB/SBBPres.html>](http://www.biosafety.be/GB/AdressesGB/SBBPres.html)

[The Biosafety Advisory Council \(BAC\) <http://www.bio-council.be/>](http://www.bio-council.be/)

[Federal Public Service Employment, Labour and Social Dialogue <http://www.employment.belgium.be/home.aspx>](http://www.employment.belgium.be/home.aspx)

3. Germany

Biosafety – National Legislation

Work with Biological Agents

The Federal Ministry of Labour and Social Affairs is responsible for occupational health and safety legislation in Germany. The core element of German health and safety legislation is the Labour Protection Act (Arbeitsschutzgesetz), which came into force on 7 August 1996. This act is supplemented by a series of specialized ordinances. Directive 2000/54/EC was implemented through the German law entitled "Ordinance on safety and health protection at work involving biological agents" (Biological agent's ordinance – BioStoffV).

The advisory committee on biological agents (Ausschuss für Biologische Arbeitsstoffe, [ABAS](#)) provides technical and scientific advice on all aspects of biosafety, develops technical rules and guidelines regarding occupational health and safety involving biological agents and is responsible for the national classification of biological agents in risk groups.

The Federal Ministry is supported by the Federal Institute for Occupational Safety and Health ([BAuA](#)). The competent occupational health and safety authorities of the Bundesländer are responsible for enforcement.

Contained use of GMM/GMO

The Federal Ministry of Food, Agriculture and Consumer Protection is responsible for legislation in the field of genetic engineering in Germany. Directives 90/219/EEC and 98/81/EC are implemented through the Genetic Engineering Act, by the Second Law, of 16 August 2002, which amended the Gene Technique Law.

The [Federal Office of Consumer Protection and Food Safety](#) (BVL) is the leading federal authority and is mandated as the national competent authority according to the Genetic Engineering Act (Gentechnikgesetz) and Ordinances based on this Act. The BVL advises the Federal Government as well as the Bundesländer and their bodies on issues of biological safety in genetic engineering.

Risk assessment

Regulation of both Biological Agents and GMM/GMO use relies on Risk Assessment. The criteria for the Risk Assessment and the corresponding safety precautions are laid down in the Biological Agents Ordinance or in the Gene Technology Safety Regulations. Employers are required to notify activities with biological agents of risk groups 2, 3 and 4. They must also notify activities with genetically modified organisms of risk groups 1 and 2 or obtain a licence from the competent authority for activities with GMOs of risk groups 3 and 4. The notifying organisation submits a standardized form, describing the activities, a risk assessment and safety precautions, to the Competent Authority of the relevant Bundesland. For GMOs, the Central Commission for Biological Safety (ZKBS) and the Bundesländer participate in the risk assessment procedure to an increasing extent as the class of the activities increases.

The Central Commission for Biological Safety provides general guidelines on safety precautions for common activities plus underlying criteria for comparability, which simplify and accelerate the approval process.

Inspections

In Germany, inspections fall under the competence of the Bundesländer and include

examination of logbooks and related activities. GMO samples may be taken as a means of examining the identity of organisms and the effectiveness of containment. Approvals can be suspended or revoked where deficiencies in organizational and safety measures are discovered.

Competent authorities on GMM/GMO

[The Federal Office of Consumer Protection and Food Safety \(BVL\)](http://www.bvl.bund.de/cln_027/nn_495478/EN/Home/homepage__node.html__nnn=true)
http://www.bvl.bund.de/cln_027/nn_495478/EN/Home/homepage__node.html__nnn=true

4. France

Biosafety – National Legislation

Work with Biological Agents

France is a republic divided into 26 administrative regions. 22 are in metropolitan France (21 are on the continental part of metropolitan France; one is the territory of Corsica), and four are overseas regions.

Occupational health and workplace safety matters are administered through the Ministry of Employment. French regulations that affect the use of biohazards are found under Work Code Articles R. 231-51 to R.231-65, as last amended by Decree 2001-97 of 1 February 2001 and Decree 2001-532 of 20 June 2001.

Contained use of GMM/GMO

Directives 90/219/EEC and 98/81/EC are implemented into the national legislation.

Competent authorities on GMM/GMO

Ministry of Research

5. Ireland

Biosafety – National Legislation

Work with Biological Agents

Ireland is a republic subdivided into four provinces where the central government is largely responsible for occupational and health legislation. [The Health and Safety Authority](#) is required, under section 57 of the [Safety, Health and Welfare at Work Act 2005](#) (No. 10 of 2005) to keep under review safety and health legislation (relevant statutory provisions) and other statutes (associated statutory provisions) that have a bearing on occupational safety and health.

Ireland has implemented Directive 90/679/EEC in [S.I. No. 248/1998 — Safety, Health and Welfare At Work \(Biological Agents\) \(Amendment\) Regulations, 1998](#).

Contained use of GMM/GMO

The [environmental Protection Agency](#) (EPA) is the Competent Authority in Ireland for implementation of the GMO Regulations on the contained use, the deliberate release and transboundary movement of GMOs into the environment.

In Ireland Directives 90/219/EEC and 98/81/EC are transposed into Irish legislation through the Genetically Modified Organisms (Contained Use) Regulations 2001, S.I. No. 73 of 2001. In accordance with consent conditions issued in respect of GMM's activities and Article 38 of the [Genetically Modified organisms, GMO \(Contained Use\) Regulations, S.I. No 73 of 2001](#), all users of GMO/GMM contained use activities are required to submit annual reports to the EPA detailing any changes in their GMO Register Entry, Risk Assessment and/or containment measures applied.

Risk assessment

Every employer (Section 19 of the Safety, Health and Welfare at Work Act 2005) has to carry out a risk assessment when working with biological agents.

Ireland has implemented a risk assessment format similar to that set out in the risk assessment guidelines produced by the EU Commission (98/81/EC). Examples of risk assessments for GMM activities in Classes 1 and 2 have been placed on EPA [website](#).

Inspections

Facilities are inspected for compliance with relevant consent conditions, such as avoidance of adverse effects on human health and the environment, periodic review of risk assessment and containment measures, establishment of a Biological Safety Committee and requirement to submit annual reports and keep log books.

Competent authorities on GMM/GMO

[Environmental Protection Agency \(EPA\)](#)

<http://www.epa.ie/>

6. Norway

Biosafety – National Legislation

Work with Biological Agents

The Ministry of Labour and Government Administration represented by the [Norwegian Labour Inspection Authority](#) is responsible for occupational safety and health regulations in Norway.

Directive 2000/54/EC is implemented into the national legislation regulations by Forskrift av 19.12.1997 nr 1322: [Vern mot eksponering for biologiske faktorer \(bakterier, virus, sopp m.m. på arbeidsplassen\)](#) (Regulation relating to biological factors).

Contained use of GMM/GMO

The competent authority on contained use for GMO in Norway is the Ministry of Health and Care Services represented by the [Directorate for Health \(HELSEDIR\)](#). Directives 90/219/EEC and 98/81/EC are implemented into the national legislation and transposed into Norwegian law by the [Lov om framstilling og bruk av genmodifiserte organismer m.m](#) (Gene Technology Act). The same act also implements the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. Deliberate release is the responsibility of the Ministry of the Environment. SHdir evaluates the notifications and consider the applications for contained use of GMO. The directorate also is responsible for approving facilities for such activities.

Risk assessment

Specific regulations require that notifications and applications on contained use of GMM are accompanied by a risk assessment. Guidelines for risk assessment are given in the regulations. The requisite containment level follows from the risk assessment.

Inspections

SHdir inspects facilities and activities according to the Gene Technology Act. Inspections are performed to ascertain that the required containment measures are met and that the activities comply with the information given in the notifications or applications.

Competent authorities on Genetically Modified Organisms (GMO)

[Directorate for Health \(HELSEDIR\)](#): <http://www.shdir.no/>

Competent authorities on occupational safety and health

[Norwegian Labour Inspection Authority \(Arbeidstilsynet\)](#)
<http://www.arbeidstilsynet.no/>

7. Sweden

Biosafety – National Legislation

Work with Biological Agents

The Work Environment Act defines the outer Swedish framework of work environment regulation and the [Swedish Work Environment Authority](#) is tasked by the Government with issuing more detailed regulations on the subject.

Directive 2000/54/EC is implemented and a transposition is given in AFS 2005:01 (Mikrobiologiska arbetsmiljörisker - smitta, toxinpåverkan, överkänslighet ([Swedish](#)))
Microbiological work environment risks– infection, toxigenic effect, hypersensitivity ([English](#)).

Contained use of Genetically Modified Organisms (GMO)

The responsibility for different contained gene technology activities under the Swedish Environmental Code is shared among several authorities in Sweden; The [Swedish Work Environment Authority](#) (Micro-organisms including cell cultures of higher organisms), [National Board of Fisheries](#) (Aquatic organisms other than micro-organisms) and [Swedish Board of Agriculture](#) (Other organisms).

Directives 90/219/EEC and 98/81/EC are implemented into the legislation via the Swedish Environmental code (law). The Swedish Environmental Code defines contained use as "an activity in which organisms are genetically modified, cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the public and the environment and provide a high degree of security for the public and the environment" ([chapter 13, section 5](#)).

Genetically Modified Organisms (Contained Use) Ordinance is given in SFS 2000:271 [Förordning om innesluten användning av genetiskt modifierade organismer](#). A notification or an application for permit use of GMM must be sent to The Swedish Work Environment Authority, depending on category. The rules are specified in AFS 2000:5: Arbetsmiljöverkets föreskrifter om innesluten användning av genetiskt modifierade mikroorganismer ([Swedish](#)) (The Swedish Work Environment Authority's Regulations on Contained Use of Genetically Modified Micro-Organisms ([English](#))).

Risk assessment

All contained use of GMM must be risk assessed in advance. Protection measures are chosen with reference to what could happen if GMM would escape from the containment. The procedure for risk assessment is described in App. 1 to the Provisions AFS 2000:5. Further guidance on risk assessment is included in the Recommendations accompanying App. 1, AFS 2000:5.

For more information on how to comply with the rules concerning contained use of GMMs see the [Guidance](#) published by the Swedish Work Environment Authority

Inspections

The administrative officers of the notification perform inspections.

Competent authorities on GMM/GMO

[Arbetsmiljöverket](http://www.av.se/) (The Swedish Work Environment Authority)
<http://www.av.se/>

[Fiskeriverket](http://www.fiskeriverket.se/) (National Board of Fisheries)
<http://www.fiskeriverket.se/>

[Jordbruksverket](http://www.sjv.se/) (Swedish Board of Agriculture)
<http://www.sjv.se/>

[Genvägen](http://www.gmo.nu/) (Website of the Swedish gene technology authorities)
<http://www.gmo.nu/>

8. Switzerland

Biosafety – National Legislation

Work with Biological Agents

Regarding biological safety, the European directives 2000/54/EC, /219/EEC and 98/81/EC are the basis for the implementation of national legislation. [The Federal Office of Public Health](#) (FOPH) is the national authority in health matters.

The protection of people and the environment against serious damage resulting from major accidents involving micro organisms is regulated by the Ordinance on Protection Against Major Accidents of 27 February 1991. Protection of working personnel is also regulated by The Ordinance on Occupational Safety in Biotechnology of 25 August 1999 OOSB.

Contained use of GMM/GMO

The competent office for organisms pathogenic for humans is the [FOPH](#). For all other activities, it is the [Federal Office for the Environment](#) (FOEN). The Federal Coordination Centre for Biotechnology (FCCB) is the entry and exit point for all notifications and licence applications for authorisation under the Ordinance on the Contained Use of Organisms. The handling of GMO is governed by the Gene Technology Law, while the handling of non-GM pathogenic organisms is governed by the Federal Laws on Epidemics and Environmental Protection.

The [Ordinance on the Contained use of organisms of 25 August 1999 \(as of 23 November 1999\)](#) regulates the contained use of organisms, in particular genetically modified or pathogenic organisms.

Whoever performs activities with pathogenic or genetically modified organisms has to notify (activities with organisms of risk group 1 and 2, no/negligible or low risk) or obtain a licence from the competent authority (activities with organisms of risk group 3 and 4, moderate or high risk). The FCCB distributes the incoming documents to the offices and bodies stated in the ordinances for consultation. The competent bodies then decide, based on the statements, on the classification and communicate their decision to the project leader (class 1 and 2) or they deliver a permit (class 3 and 4).

The [Swiss Federal Veterinary Office](#) (SFVO) aims to control and monitor animal diseases which pose a risk to livestock, which could be transmitted to humans, could have a serious economic impact or could compromise the international trade. Therefore all activities in a laboratory involving highly contagious animal diseases (OIE list A) require an authorization of the SFVO. The legal basis is the law and the ordinance on animal diseases (Tierseuchengesetz und -verordnung). Based on this legislation, the risk assessment of the applicant (according to the contained use ordinance) and the current situation with regard to highly contagious animal diseases the application will be examined. An authorization will only be issued if the cantonal veterinary office agrees.

Risk assessment

The project leader who intends to carry out an activity has to notify or submit an authorization application to the FCCB. This can be done electronically by accessing the internet database [ECOGEN](#). The project leader has to assess the risk and classify the activities according to the risk group of the organisms (1 to 4), the genetic modifications and the kind of activity. There are 4 different classes. Class 1 is considered to imply no or negligible risk to the people and the

environment and class 4 is considered to imply a high risk. Class 2 and 3 imply a low or moderate risk, respectively. According to the class of the activity, safety measures must be implemented ranging from safety level 1 to 4. General safety measures have to be implemented for all classes of activities. The internet page of the FCCB hosts many relevant documents and information's on biosafety, e.g. lists of organisms, guides for biosafety officers and safety concepts.

Inspections

The inspection and the control of the safety measures are done by the local (cantonal) authority. Notification, authorization and inspection procedure for activities with genetically modified and pathogenic organisms in research and diagnostic laboratories, greenhouses and production facilities according to Swiss law is outlined on this [link](#) on the website <http://www.biosafety-europe.eu>.

Competent authorities on GMM/GMO

Cantonal Offices (German, French and Italian only)

http://www.afu.ch/d_afu_adressen.cfm?

[Nav.Command=Fachbereiche&Module.Method=showFachbereiche&fach_id=8](#)

ECOGEN

<http://www.ecogen.ch/>

Federal Coordination Centre for Biotechnology

<http://www.bafu.admin.ch/biotechnologie/01744/01745/index.html?lang=en>

Federal Office for the Environment (FOEN)

<http://www.bafu.admin.ch/index.html?lang=en>

Federal Office of Public Health (FOPH)

<http://www.bag.admin.ch/index.html?lang=en>

Federal Veterinary Office (FVO)

<http://www.bvet.admin.ch/index.html?lang=en>

Federal Office for Agriculture (FOAG)

<http://www.blw.admin.ch/index.html?lang=en>

SUVA

<http://www.suva.ch/>

Swiss Expert Committee for Biosafety

<http://www.efbs.admin.ch/en/index.html>

9. The Netherlands

Biosecurity – National Legislation
(no legislation up till now)

Biosafety – National Legislation

Work with Biological Agents

[The Ministry of Social Affairs and Employment](#) (SZW) is responsible for the EU directive 2000/54/EC protection of workers from risks related to exposure to biological agents at work.

The government has established the legal framework within which employers and employees are expected to fulfil their responsibilities. The Dutch Safety and Health Act (Arbowet) contains a code of conduct for safety & health policy. The Labour Inspectorate ensures compliance with the legislation. A number of financial measures have been implemented to reward good conduct and to penalise bad practices. Besides that, the Ministry encourages executives and workers to cooperate and take an active role. The Ministry also encourages all parties involved to actively increase expertise.

Contained use of GMM/GMO

The [Ministry of Housing, Spatial Planning and the Environment](#) (VROM) is a political organization operating under the leadership of the Minister and State Secretary. VROM is responsible for the EU directives on environmental safety of GMOs and regulation of the traceability and labelling of GMOs. The [Ministry of Health, Welfare and Sport](#) (VWS) is responsible for the regulation of genetically modified food and feed. The [Ministry of Agriculture, Nature and Food Quality](#) is also involved in all aspects. Dutch legislation is based on Directive 90/219/EC as amended by 98/81/EC on the contained use of GMMs and 2001/18/EC on deliberate release into the environment. These two directives have been implemented in Dutch legislation at several levels:

Environmental Management Act and Dangerous Substances Act
Decree on Genetically Modified Organisms
Ministerial Regulation on Genetically Modified Organisms

The Ministerial Regulation of GMOs is linked to the GMO Decree and lays down more detailed (technical) rules which apply primarily to the contained use of GMOs. The GMO Decree states that activities involving GMOs are only allowed with a permit. Permits are issued by the Ministry of Housing, Spatial Planning and the Environment. The VROM website on [biosafety](#) provides information on GMO legislation and national and international biosafety activities. It contains a database with up-to-date information on licence applications. However the related Website is only available in Dutch.

In the Netherlands all genetic modified organism are regulated (micro-organisms, animals and plants).

Risk assessment

The notifier carries out a risk assessment; which is then forwarded to the Competent Authority with a proposal for the level of containment. For GMOs a permit is required to start activities. For working with biological agents only a notification is sufficient. For both procedures a risk-assessment has to be performed.

Inspections

The VROM Inspection monitors both activities on contained use as well as deliberate release. The Labour Inspectorate monitors compliance with occupational safety and health legislation and regulations. It investigates violations of worker safety, takes action and provides politically relevant information.

Competent authorities on GMM/GMO

[The Ministry of Housing, Spatial Planning and the Environment \(VROM\)](http://international.vrom.nl/pagina.html?id=5450&ref=http://www.sharedspaces.nl/pagina.html?id=10535)

<http://international.vrom.nl/pagina.html?id=5450&ref=http://www.sharedspaces.nl/pagina.html?id=10535>

[Ministry of Health, Welfare and Sport \(VWS\)](http://www.minvws.nl/en/)

<http://www.minvws.nl/en/>

[Ministry of Agriculture, Nature and Food Quality \(LNV\)](http://www.minlnv.nl/portal/page?_pageid=116,1640354&_dad=portal&_schema=PORTAL)

[http://www.minlnv.nl/portal/page?
_pageid=116,1640354&_dad=portal&_schema=PORTAL](http://www.minlnv.nl/portal/page?_pageid=116,1640354&_dad=portal&_schema=PORTAL)

Competent authorities on biological agents

[Ministry of Social Affairs and Employment \(SZW\)](http://www.employment.gov.nl/)

<http://www.employment.gov.nl/>

BSO platform

More than 10 years ago a platform for Biosafety officers was established. The aim of this platform is to exchange information and experience on biosafety issues. The BSO platform has a formal contact to the competent authority for GMO's (Ministry of VROM) and is often invited to discuss new legislation on GMO's at an early stage.

10. United Kingdom (UK)

Biosecurity – National Legislation

Legal requirements to impose secure storage and use of dangerous pathogens and toxins are listed in Schedule 5 of Part 7 of the Anti Terrorism, [Crime and Security Act 2001](#) and the Security of Pathogens and Toxins (Exceptions to Dangerous Substances Regulations 2002).

The original Schedule 5 was a ‘classical’ list of agents (including pathogens and toxins) from state biological warfare programmes. In May 2007 Schedule 5 was extended to include animal pathogens. The substances covered by the legislation have since been reviewed. The current full list of materials contained within Schedule 5 has been published in the Pathogens and Toxins Guidance ATCSA 2001 Schedule 5 Order 2007 Notes (SI 2007/929).

Biosafety – National Legislation

Work with Biological Agents

The Health and Safety Commission (HSC) is responsible for health and safety regulation in UK. The [Health and Safety Executive \(HSE\)](#) and local government are the enforcing authorities who work in support of the Commission.

Directive 2000/54/EC is implemented in the UK by means of The Approved List of Biological Agents made under section 15 of the [Health & Safety at Work Act \(HSWA\) 1974](#). The regulations are set out in [The Control of Substances Hazardous Regulations to the Health Regulations 2002](#) (COSHH).

Contained use of GMM/GMO

The UK have separate regulatory frameworks to govern work with human and animal pathogens. The regulations are separate but overlapping. The [Health and Safety Executive \(HSE\)](#) operates and enforces legislation that aims to control the risks to human health and the environment arising from activities involving contained use of GMOs.

Directives 90/219/EEC and 98/81/EC are implemented in UK regulations: For Great Britain (England, Wales and Scotland) the [Genetically Modified Organisms \(Contained Use\) Regulations 2000](#) (GMO(CU)) came into force on 15 November 2000; The Regulations in Great Britain have subsequently been amended by the [GMO \(Contained Use\) \(Amendment\) Regulations 2002](#) and the GMO (Contained Use) (Amendment) Regulations 2005.

In Northern Ireland the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001 came into force on 25 September 2001.

For Gibraltar - the Public Health (Genetically Modified Organisms (Contained Use)) Regulations 2001, came into force on 26 April 2001.

For more information about the legislation see: [3-year report from the UK Competent Authorities on experiences arising from the implementation of Directive 98/81/EC, which amended Directive 90/219/EEC](#) (see <http://www.biosafety-europe.eu>).

The [Department of the Environment, Food and Rural Affairs \(DEFRA\)](#) leads policy and enforcement relating to the deliberate release of animal GMOs into the environment. [The](#)

[Specified Animal Pathogens Order 1998 \(SAPO\)](#) is made under the Animal Health Act 1981. The main purpose of SAPO is to prevent release of dangerous pathogens into the environment where they may cause a serious animal (or human) disease.

Risk assessment

The COSHH and GMO(CU) regulations are both based on the requirement that the duty holder prepares a risk assessment. Scientific and technical guidance on risk assessments have been published by the Competent Authority and are available on the internet on the HSE [Website](#).

Inspections

The HSE's Biological Agents Unit (BAU) is responsible for regulating facilities and work activities where highly pathogenic GMO are intentionally handled. BAU inspectors enforce COSHH and GMO(CU) regulations. In 2007, BAU had 26 staff of which 15 were specialist inspectors. The inspectorate has the authority to issue notices to prohibit or give timetables for improvement to activities in laboratories if they do not comply with national legislation.

Inspections of SAPO laboratories are carried out by DEFRA or the Veterinary Laboratories Agency (VLA). However, after the release of Foot and mouth disease (FMDV) from the Pirbright site it was recommended that the HSE carry out all inspections and that a single system for laboratory classification should be introduced.

Competent authorities on Genetically Modified Organisms (GMO)

Health and Safety Executive (HSE)

<http://www.hse.gov.uk/>

Department of the Environment, Food and Rural Affairs (DEFRA)

<http://www.defra.gov.uk/>

The National Assembly for Wales

<http://new.wales.gov.uk/>

Scottish Executive

<http://www.scotland.gov.uk/>

Government Advisory Committees

[Scientific Advisory Committee on Genetic Modification](#) (contained use)

<http://www.hse.gov.uk/aboutus/meetings/sacgmcu/index.htm>

[Advisory Committee on Releases to the Environment \(ACRE\)](#)

<http://www.defra.gov.uk/environment/acre/index.htm>

[Gene Therapy Advisory Committee \(GTAC\)](#)

<http://www.advisorybodies.doh.gov.uk/genetics/gtac/index.htm>

[United Kingdom Xenotransplantation Interim Regulatory Authority \(UKXIRA\)](#)

<http://www.advisorybodies.doh.gov.uk/ukxira/>

[Agriculture and Environment Biotechnology Commission](#)

<http://www.aebc.gov.uk/>

[Advisory Committee on Dangerous Pathogens \(ACDP\)](#)

<http://www.hse.gov.uk/aboutus/meetings/acdp/index.htm>

The ACDP are an expert committee made up of microbiologists, medical doctors, employers and union representatives. Their duties include producing a current list for the categorisation of microbial agents on the basis of knowledge about their pathogenesis, transmissibility and history of laboratory infection ([The Approved List of biological agents](#)). They issue a wide range of guidance on protection against pathogenic agents in laboratories, hospitals and other environments. Some of this guidance may be agent specific (e.g. for Transmissible Spongiform Encephalopathies, TSEs) or may be aimed at different working environments. Recent publications include a detailed document on containment level 4, advice on leak testing laboratories prior to fumigation and on the use of isolators to contain laboratory animals. While guidance is not as prescriptive as legislation, when a containment laboratory is inspected by regulatory body, it may be necessary to demonstrate that it complies with published guidance or uses alternative means to afford the same level of worker protection. Current publications on legislation and guidance (both electronic and available for purchase in hard copy) are shown on the HSE [website](#).

Post Pirbright

A number of reports on the release of FMDV from the Pirbright site have been published ([Investigations and reviews into the outbreak](#)). The Callaghan report has made recommendation for altering the regulatory framework for animal pathogens in the UK. These recommendations have been generally accepted by the UK government. This will probably lead to a change in the UK regulatory framework during 2008/09.