

NATIONAL LAWS

The overview (see Table 2) covers areas such as handling (potentially) infectious materials (human, animal, and pathogen origin), data protection, adherence to ethical principles, and the conduct of clinical trials.

Table 2: Overview of national laws applicable for biospecimen handling

The following national laws, sorted by EU and non-EU countries and then in alphabetical order, are essential for the handling, collection, processing, storage, provision and transport of biospecimens (human, animal and pathogen origin), with GMOs occupying a special position. In addition to the handling of biospecimens, regulations governing the conduct of clinical trials and medical products also play a major role in infectious disease research (although the intention was to be comprehensive, we make no claim to completeness).

EU countries	
Austria	
Legal information system https://www.ris.bka.gv.at/ (German)	
Animals	- Animal examinations under anesthesia (without clinical indication but for scientific purpose) have to be in accordance with Animal Experiments Act 2012, Federal Law Gazette I No. 114/2012
Data Protection	- Federal Act concerning the Protection of Personal Data (DSG) - Datenschutzgesetz 2000
Chemicals	- Chemicals Act (Chemikaliengesetz)
GMOs	- Genetic Engineering Act (Gentechnikgesetz)
Infectious Disease	- Infection Protection Act (Epidemiegesetz)
Occupational Health and Safety	- Austrian Occupational Safety and Health Act (Arbeiterinnenschutzgesetz)
Belgium	
Legal information system	

http://www.ejustice.just.fgov.be/cgi_loi/loi.pl (French)
http://www.ejustice.just.fgov.be/cgi_wet/wet.pl (Dutch)

Animals	<ul style="list-style-type: none">- Protection and welfare of animals (last modified 2018)- Royal Decree of 14th November 1993 related to the protection of experimental animals
Data Protection	<ul style="list-style-type: none">- Law on electronic communication (amended in 2014)
GMOs	<ul style="list-style-type: none">- Royal Decree regulating the deliberate release into the environment and the placing on the market of genetically modified organisms or products containing GMOs (2004)- The relevant European legislation has been transposed at regional level as a part of the Regional Environmental laws for classified installations. The scope of the Belgian regional legislation is broader than the scope of the EU Directive since it includes, in addition to genetically modified microorganisms (GMMs), genetically modified organisms (GMOs) and pathogenic organisms (Contained Use of GMOs and Pathogens Belgian Biosafety Server)
Human Material	<ul style="list-style-type: none">- Law on Biomedical Research 14/2007 July 3rd on Biomedical Research- Law of 19th December 2008 on the procurement and use of human biological material intended for human medical applications or for scientific research purposes
Occupational Health and Safety	<ul style="list-style-type: none">- Law of 4th August 1996 on well-being of workers in the performance of their work ("Code on Well-being at Work" (le Code sur le bien-être au travail)).

Bulgaria

Legal information system

<https://dv.parliament.bg/DVWeb/index.faces>

Data Protection

- Law for Protection of Personal Data (<https://www.cdpd.bg/en/>)

GMOs

- The Law on Genetically Modified Organisms (2005)

Czech Republic

Legal information system

<https://www.mvcr.cz/web-legislativa.aspx> (Czech)

Animals	<ul style="list-style-type: none"> - Law No 246/1992 Coll. on protection of animals against cruelty (The breeding and use of animals) - Decree No 419/2012 on protection of experimental animals (use of laboratory animals) - Decree No 22/2013 on protection of animals against cruelty education
Chemicals	<ul style="list-style-type: none"> - Law No. 350/2011 Coll., On Chemical Substances and Chemical Mixtures
Data Protection	<ul style="list-style-type: none"> - Act No. 11/2019 on changes related to Act on Processing Personal Data - Act No. 110/2019 on Processing of Personal Data
GMOs	<ul style="list-style-type: none"> - Law No. 78/2004
Occupational Health and Safety	<ul style="list-style-type: none"> - Law No. 309/2006 on further requirements with regard to occupational safety and health.

Denmark

Legal information system

<https://www.retsinformation.dk/> (Danish)

Animals	<ul style="list-style-type: none"> - Danish legislation (LBK nr 253, 08/03/2013) (use and housing of animals)
Clinical Trials	<ul style="list-style-type: none"> - The Danish Law on clinical trials with medicinal products: Bekendtgørelse af lov om kliniske forsøg med lægemidler, LBK nr. 1252 af 31/10/2018 - The Danish Law on clinical investigations with medical device: Lov nr. 1853 af 09/12/2020 om videnskabsetisk behandling af kliniske afprøvning af medicinsk udstyr.
Data Protection	<ul style="list-style-type: none"> - Act on Processing of Personal Data
GMOs	<ul style="list-style-type: none"> - The Environment and Genetic Engineering Act No.9 of 4/1/2017

Finland

Legal information system

<https://www.finlex.fi/en/>

Animals	<ul style="list-style-type: none"> - Law on the protection of animals used for scientific or educational purposes (497/2013)
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	- Decree on the protection of animals used for scientific or educational purposes (564/2013)
Data Protection	- Personal Data Act 523/1999
GMOs	- Law 377/1995 and the Decrees 928/2004 and 184/2005 regulate the use and storage of genetically modified organisms.
Medical research	- Medical Research Act (488/1999)
Occupational Health and Safety	- Government Decree on Protection of Workers from the Dangers of Biological Agents (933/2017).

France

Legal information system

<https://www.legifrance.gouv.fr/> (French)

Animals	<ul style="list-style-type: none"> - Order of 1st February 2013 laying down the conditions for the approval, layout and operation of establishments that use, breed or supply animals used for scientific purposes and their controls (Arrêté du 1er février 2013) - Order of April 2002 on health conditions for the import and transit in France of products derived from animals and pathogenic agents, mentioned in article L. 236-1 of the rural code, intended exclusively for technical or pharmaceutical use from third countries (Arrêté du 5 avril 2002) – animal-by-product regulation
Biomedical Research	- Public Health Code in Regulatory Section: Additional Book II, Articles R.2001 to R.2053. Law 2004-801.
Chemicals (Risks)	- Code du travail: Articles Article R4412-1 à R4412-160
Classification of pathogens	<ul style="list-style-type: none"> - Order of 17th April 1997 amending the order of 18th July 1994 establishing the list of biological pathogens (Arrêté du 17 avril 1997) - Order of 30th April 2012 establishing the list of micro-organisms and toxins provided for in Article L. 5139-1 of the Public Health Code (Arrêté du 30 avril 2012)

	<ul style="list-style-type: none"> - Order of 30th June 1998 laying down the procedures for implementing the Convention on International Trade in Endangered Species of Wild Fauna and Flora and European Council Regulation (EC) No 338/97 and European Commission Regulation (EC) No 939/97 (Arrêté du 30 juin 1998)
Data Protection	<ul style="list-style-type: none"> - Law relating to the protection of individuals against the processing of personal data - Law 78-17 of January 6, 1978 on data processing, data files and individual liberties, as amended
Environment	<ul style="list-style-type: none"> - Environment Code, Book 5, Book V: Prevention of pollution, risks and nuisances (Articles L501-1 to L597-46), Title 3 (Code de l'environnement)
GMOs	<ul style="list-style-type: none"> - Decree no. 2021-1905 of 30th December 2021 implementing Order no. 2021-1325 of 13th October 2021 reforming the assessment of biotechnologies and simplifying the procedure applicable to the contained use of genetically modified organisms presenting no or negligible risk (Décret n° 2021-1905 du 30 décembre 2021) - Order of 25th January 2022 relating to the technical dossier required for the contained use of genetically modified organisms provided for in Articles R. 532-6, R. 532-14, R. 532-26, as well as the risk assessment dossier provided for in Article L. 532-3 of the Environment Code (Arrêté du 25 janvier 2022)
Human material	<ul style="list-style-type: none"> - Use of human biological materials in France is regulated by the Donation and Use of the Components and Products of the Human Body, Articles L 1211-1 to 1274-3 (2004).
Occupational health and safety	<ul style="list-style-type: none"> - French Labour Code: Articles R4421-1 to R4421-5 (Code du travail) - Order of 27th December 2017 on the list of biological pathogens and the technical prevention measures to be implemented in laboratories where workers are likely to be exposed to biological pathogens (Arrêté du 27 décembre 2017)
Transport	<ul style="list-style-type: none"> - Order of 29th May 2009 on the transport of dangerous goods by land (known as the "TDG Order") (Arrêté du 29 mai 2009)
Waste	<ul style="list-style-type: none"> - Public Health Code (Code de la santé publique) - Order of 20th May 2014 amending the order of 7th September 1999 on the control of disposal channels for waste from care activities involving infectious and similar risks and anatomical parts and the order

	<p>of 7th September 1999 on storage procedures for waste from care activities involving infectious and similar risks and anatomical parts (Arrêté du 20 mai 2014)</p> <ul style="list-style-type: none"> - Order of 7th September 1999 on the control of disposal channels for waste from healthcare activities involving infectious and similar risks and anatomical parts (Arrêté du 7 septembre 1999)
Germany	
<p>Legal information system https://www.gesetze-im-internet.de/index.html (German)</p>	
Animals	<ul style="list-style-type: none"> - Animal Welfare-Act (Tierschutzgesetz – TierSchG 18th May 2006) - Animal By-Products Disposal Act (Tierische Nebenprodukte-Beseitigungsgesetz – TierNebG 25th January 2004) - Ordinance on Animal Protection and Laboratory Animal (Tierschutz-Versuchstierverordnung – TierSchVersV – 1st August 2013)
Chemicals	<ul style="list-style-type: none"> - Chemicals Act - Law on protection against hazardous substances (Chemikaliengesetz – ChemG 28th August 2013) - Ordinance on Biological Agents (Biostoffverordnung – BioStoffV 15th July 2013)
Data Protection	<ul style="list-style-type: none"> - Federal Data Protection Act (Bundesdatenschutzgesetz – BDSG 23rd June 2021)
GMOs	<ul style="list-style-type: none"> - Genetic Engineering Act (Gentechnikgesetz – GenTG 27th September 2021) - Ordinance on Genetic Engineering Safety (Gentechnik-Sicherheitsverordnung – GenTSV 12th August 2019) - Ordinance on Records for Genetic Engineering Work and for Releases (Gentechnik-Aufzeichnungsverordnung – GenTAufzV 28th April 2008)
Human material	<ul style="list-style-type: none"> - Act ensuring protection of embryos in connection with the importation and utilization of human embryonic stem cells (Stammzellgesetz – StZG 29th March 2017)
Infectious Disease	<ul style="list-style-type: none"> - Infection Protection Act (Infektionsschutzgesetz – IfSG 20th December 2022)

Medicinal products	<ul style="list-style-type: none"> - Medicinal Products Act / Pharmaceutical Products Act (Arzneimittelgesetz – AMG 20th December 2022) - Act on Medical Devices (Medizinproduktegesetz – MPG 19th June 2020)
Occupational Safety and Health	<ul style="list-style-type: none"> - German Occupational Safety and Health Act (Arbeitsschutzgesetz – ArbSchG – 31st May 2023) - Regulation on the protection from ionizing radiance (Strahlenschutzverordnung – StrSchV 8th October 2021)
Technical Rule for Biological Agents (TRBAs)	<p>In Germany technical rules serve to concretize laws and ordinances on occupational health and safety. They contain recommendations and technical suggestions on how the respective requirements can be implemented. They reflect the state of the art in technology, occupational medicine and occupational hygiene as well as other established occupational science findings at the time of publication. In general, technical rules are not legally binding. If the technical rules are complied with, the employer can assume that the underlying requirements of the laws and regulations are fulfilled (presumption of conformity).</p> <p>The Federal Institute for Occupational Safety and Health (BAuA) - http://www.baua.de</p>
Human Body Fluids	<ul style="list-style-type: none"> - TRBA 100 Protective measures for targeted and non-targeted activities with biological working substances - TRBA 200 Expertise requirements - TRBA 213 Waste collection
Human Tissue	<ul style="list-style-type: none"> - TRBA 100 Protective measures for targeted and non-targeted activities with biological working substances - TRBA 200 Expertise requirements - TRBA 213 Waste collection
Animals	<ul style="list-style-type: none"> - TRBA 100 Protective measures for targeted and non-targeted activities with biological working substances - TRBA 120 Laboratory animal husbandry

	<ul style="list-style-type: none"> - TRBA 200 Expertise requirements - TRBA 213 Waste collection - TRBA 260 Protective measures for activities with biological agents in veterinary medicine and comparable activities - TRBA 406 Sensitizing substances for the respiratory tract - Ausschuss für Biologische Arbeitsstoffe (ABAS) 603 Protective measures for activities involving transmissible Spongiform Encephalopathy (TSE) associated agents in TSE laboratories - ABAS 608 Recommendation of special measures to protect employees from infections caused by highly pathogenic avian influenza viruses (classical avian influenza, bird flu)
Pathogens	<ul style="list-style-type: none"> - TRBA 100 Protective measures for targeted and non-targeted activities with biological working substances - TRBA 200 Expertise requirements - TRBA 213 Waste collection - TRBA 240 Protective measures during activities with microbially contaminated archive material - TRBA 255 Protective measure in case of occurrence of insufficiently vaccine-preventable respiratory viruses with pandemic potential - TRBA 406 Sensitizing substances for the respiratory tract - TRBA 450 Classification criteria for biological agents - TRBA 460 Classification of fungi into risk groups - TRBA 462 Classification of viruses into risk groups - TRBA 464 Classification of parasites into risk groups - TRBA 466 Classification of prokaryotes (Bacteria and Archaea) into risk groups - TRBA 468 List of cell lines and activities with cell cultures

	<ul style="list-style-type: none"> - ABAS 605 Activities involving poliovirus-infected and/or potentially infectious material, including the safe storage of poliovirus in laboratories
GMOs	<ul style="list-style-type: none"> - TRBA 100 Protective measures for targeted and non-targeted activities with biological working substances - TRBA 200 Expertise requirements - TRBA 213 Waste collection
Greece	
Legal information system https://www.et.gr/ (Greek)	
Animals	<ul style="list-style-type: none"> - Presidential Decree No 56/2013 (Governmental Gazette No A' 106) (guidelines referring to the protection of animals used for experimental and other scientific purposes) - Law No 2015/1992 (Governmental Gazette No A' 30) (protection of vertebrates used in experimental or other scientific purposes) - Presidential Decree No 184/1996 (Governmental Gazette No A' 137) (Annex III of the Decree referring to the hygiene conditions and the necessary health controls)
Data Protection	<ul style="list-style-type: none"> - Law No. 4624/2019 Hellenic Data Protection Authority (HDP A) - Data Protection Act 2472/1997
GMOs	<ul style="list-style-type: none"> - Revised Ministerial Decision No 11642/1943/2002 (Governmental Gazette No B' 831) - Law 3233.2004 / Governmental Gazette No A' 51 - Article 3 of the <i>Cartagena protocol on Biosafety</i> (regarding GMOs and their "contained use" conditions)
Hungary	
Legal information system https://njt.hu/	

Animals	<ul style="list-style-type: none"> - First act of animal protection (last consolidated 15 April 2015) - Decree No. 40 of 2013 (Il. 14.) Korm of the Government on animal testing (implementing Law No. XXVIII of 1998 on animal protection. 07 Apr 2015, Act No. XLVI of 2008 on food chain and its control. 14th Mar 2014 and Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes. 22th Sep 2010)
Data Protection	<ul style="list-style-type: none"> - Act CXII of 2011 on the right to informational self-determination and on the freedom of information - Act CVIII of 2001 on the certain aspects of electronic commerce services and information society services
GMOs	<ul style="list-style-type: none"> - The XXVII Law on Genetic Engineering (1998)
Occupational Health and Safety	<ul style="list-style-type: none"> - Act 11/2004 amending Act 93/1993 on occupational safety and health
Ireland	
Data Protection	<ul style="list-style-type: none"> - Data Protection Act 2018
GMOs	<ul style="list-style-type: none"> - The Environmental Protection Agency Act 1992
Italy	
Legal information system https://www.normattiva.it/?language=en (Italian)	
Animals	<ul style="list-style-type: none"> - Legislative Decree 26/2014, "Implementation of UE Directive n. 2010/63/UE on the protection of animals used for scientific purpose"
Data Protection	<ul style="list-style-type: none"> - Legislative Decree 101/2018 Legislative Decree that adapts the Italian legislation to the GDPR 2016/679 - Legislative Decree 196/2003 Italian personal data protection code
Human materials	<ul style="list-style-type: none"> - Law n. 675 dated 31.12.1996 (Use of Human biological materials) - Law n. 10/2020 "Rules relating to the directives of one's body and tissues post-mortem for study, training, and scientific research purposes"

	- Law n. 219/2017 concerning “Rules on informed consent and advance directives”
GMOs	- The Environmental rules – Legislative Decree of 3 April 2006, no 152
Research	- Legislative Decree n 211 of the 24.06.2003 (Good Clinical Practice.)
Transport	- Ministry of Health Circular No. 3 05/08/2003 (Regulation about transport of infectious samples)
Occupational Health and Safety	- Legislative Decree 81/2008. on the protection of workers from risks related to exposure to biological agents at work
Others	- Legislative Decree 152/2006 concerning the ambient safety - Presidential Decree 254/2003 that regulates the medical waste management.

Latvia

Legal information system

<https://www.vestnesis.lv/> (Latvian)

Data Protection	- Personal Data Processing Law (last amended 6 th May 2021) - Amendments to the Electronic Communications Law - point 2
Genetic Research	- Human Genome Research Law (last amended 2 nd Nov 2017)
GMOs	- The Law on Circulation of Genetically Modified Organisms (2007)

Lithuania

Legal information system

https://www.lrs.lt/dokpaieska/forma_1.htm

Biomedical Research	- Law on Ethics of Biomedical Research (2001, last amended in 2016) - Law on Legal Protection of Personal Data (1996, last amended in 2017) - Decree on the Procedure to Issue Approvals to Conduct Biomedical Research, No. V-2 (2008)
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	<ul style="list-style-type: none"> - Decree on the Detailed Requirements for the Content of a Person's Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent, No. V-28 (2016) - Decree on the Procedure for Calculating and Paying Compensation for the Expenses Incurred Due to Participation in Biomedical Research and the Time Spent, No. V-15(2016) - Decree on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor No. 745 (2000, last amended in 2016) - Decree on the List of Interventional Methods of Biomedical Research Causing a Slightly Detrimental and Temporary Impact on the Subject's Health, No. V-1483 (2014) - Decree of MOH and Ministry of Social Affairs on the Procedure for a Minor's Participation in Biomedical Research, No. V-235/A1-83(2016) - Decree on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage and Providing Information on Biomedical Research, No. V-405 (2010) - Further Decrees No. V-895 (2009), No. V-1185 (2014), No. V-1348 (2018), No. V-11 (2015), No. V-1078 (2007)
Clinical Trials	<ul style="list-style-type: none"> - Law on Pharmacy (2006, last amended in 2017) - Decree on the Procedure for Issuing Favourable Opinion to Conduct Clinical Trial on Medicinal Product, Approval for Clinical Trial on Medicinal Product, Conducting and Controlling Clinical Trials, No. 435 (2006) - Decree on the Rules of Good Clinical Practice, No. 320 (2006)
Data Protection	<ul style="list-style-type: none"> - Law on Legal Protection of Personal Data
GMOs	<ul style="list-style-type: none"> - The Law on Genetically Modified Organisms (2001)
Infectious disease	<ul style="list-style-type: none"> - Law on Prevention and Control of Infectious Diseases in Human Beings - Hygienic standard for healthcare institutions and requirements for infection control - Description of the procedures for testing for the detection of COVID-19 disease (coronavirus infection) and for carrying out serological tests

Occupational Health and Safety	<ul style="list-style-type: none"> - Law on Occupational Safety and Health of the Republic of Lithuania - Law on the adoption of provisions for the protection of workers from exposure to biological occupational risks at work
Waste	<ul style="list-style-type: none"> - Hygienic standard for Safety requirements for the management of medical waste
Netherlands	
Legal information system https://www.overheid.nl/ (Dutch)	
Animals	<ul style="list-style-type: none"> - Experiments on Animals Act (amended 18th Dec 2014)
Biomedical Research	<ul style="list-style-type: none"> - Medical Research Human Subjects Act (WMO) www.ccmo.nl/en/national-legislation-dutch - Decree of 23rd June 2003 containing rules for compulsory insurance in medical research involving human subjects (Medical Research (Human Subjects) Compulsory Insurance Decree) - Decree of 3rd January 2006, amending the Central Review of Medical Research Involving Human Subjects Decree - The Embryo Act.
Data Protection	<ul style="list-style-type: none"> - Personal Data Protection Act 2004
GMOs	<ul style="list-style-type: none"> - Environmental Protection Act - The Netherlands Commission on Genetic Modification (COGEM) - https://www.cogem.net
Human material	<ul style="list-style-type: none"> - Civil Code, Article 467 (1994) (use of human biological material) - Medical Research Involving Human Subjects Act 1998. - FAMHP - Federal Agency for Medicine and Health Products
Occupational Health and Safety	<ul style="list-style-type: none"> - Decree on Biological Agents of 17/05/1994 (Staatsblad N. 368 van 1994).

Poland

Legal information system

<https://isap.sejm.gov.pl/> (Polish)

Animals	<ul style="list-style-type: none">- Act of January 15th, 2015 on the protection of animals used for scientific or educational research (Journal of Laws of 2015, item 266)- Resolution No. 14/2016 of the National Commission for Animal Experiments of June 17th, 2016 on the marking and identification of animals
Chemicals	<ul style="list-style-type: none">- Act of February 25th, 2011 on chemical substances and their mixtures (Journal of Laws 2011 No. 63 item 322)- Regulation of the Minister of Health of July 24th, 2012 on chemical substances, their mixtures, factors or technological processes with carcinogenic or mutagenic effects in the work environment (Journal of Laws of 2016, item 1117, as amended)
Data Protection	<ul style="list-style-type: none">- Regulation of the Minister of Internal Affairs and Administration of April 29th, 2004 on documentation of personal data processing and technical and organizational conditions that should be met by devices and IT systems used to process personal data (Journal of Laws of 2004, no. 100, item 1024)- Act of May 10th, 2018 on the protection of personal data (Journal of Laws of 2018, item 1000)
Ethics	<ul style="list-style-type: none">- Ordinance of the Minister of Health and Welfare of May 11th, 1999, on detailed rules for the appointment and financing of, and procedures for the operation of, bioethics committees
GMOs	<ul style="list-style-type: none">- Act of June 22th, 2001 on modified organisms- Act of January 15th, 2015 amending the act on genetically modified organisms and certain other acts (Journal of Laws of 2015, item 277)- Regulation of the Minister of the Environment of April 11th, 2016 on the classification of microorganisms and organisms used during the contained use of GMMs and the contained use of GMOs.- Regulation of the Minister of the Environment of April 11th, 2016 on detailed types of security measures used in genetic engineering facilities

Human material	- Act of July 1st, 2005 on the collection, storage and transplantation of cells, tissues and organs (Journal of Laws of 2020, item 2134)
Laboratory	- Act of July 27th, 2001 on laboratory diagnostics (Journal of Laws of 2021, item 866) - Regulation of the Minister of Health of March 23rd, 2006 on quality standards for medical diagnostic and microbiological laboratories (Journal of Laws of 2019, item 1923)
Medical products	- Act of April 7th, 2022 on medical products (Journal of Laws of 2022, item 974, as amended) - Act of September 6th, 2001. Pharmaceutical Law (Journal of Laws of 2017, item 2211, as amended)
Occupational Health and Safety	- Act of June 26th, 1974 Labor Code (Labor Code) (Dz.U. of 2020, item 1320) - Regulation of the minister of labor and social policy of September 26th, 1997 on general health and safety regulations (Dz.U. 1997 No. 129 item 844) - Ordinance of the Minister of Economy and Labor of July 27th, 2004 on training in occupational health and safety (Journal of Laws of 2004, No. 180, item 1860, as amended) - Regulation of the Minister of Health of April 22th, 2005 on harmful biological agents for health in the work environment and health protection of workers occupationally exposed to these agents (Journal of Laws of 2005, No. 81, item 716)
Patient	- Regulation of the Minister of Health of April 6th, 2020 on the types, scope and templates of medical documentation and the method of its processing (Journal of Laws of 2020, as amended) - Act of November 6th, 2008 on patients' rights and the Patient Ombudsman (Journal of Laws of 2020, item 849)
Research	- Regulation of the Minister of Health of May 22nd, 2013 on good laboratory practice and performing tests in accordance with the principles of good laboratory practice (Journal of Laws of 2013, item 665)
Waste	- Law on waste of December 14th, 2012. (Journal of Laws of 2021, item 779)

Portugal

Legal information system

<https://diariodarepublica.pt/dr/home> (Portuguese)

Animals	<ul style="list-style-type: none"> - Decree-Law No. 1005/92 (animal housing and caretaking) - Decree-Law No. 113/2013 (provision for the implementation of Directive 2010/63/EU) - The use of animals for scientific purposes is under the authority of the Direção-Geral de Alimentação e Veterinária (DGAV) and institutional Animal Welfare Bodies.
Data Protection	<ul style="list-style-type: none"> - Law 58/2019 of August 8th – Law ensuring the implementation in the national legal order of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) - Law No. 13,709/2018 Protection of Personal Data
GMOs	<ul style="list-style-type: none"> - Decree-Law No 55/2015, of 17th April - Contained use of micro-organisms and genetically modified organisms (Establishes the measures for the contained use of genetically modified micro-organisms and genetically modified organisms, with a view to protecting human health and the environment, transposing Directive no. 2009/41/EC, of the European Parliament and of the Council, of 6th May 2009)

Slovakia

Legal information system

<https://www.slov-lex.sk/web/en>

Data Protection	<ul style="list-style-type: none"> - Act 18/2018 on the Protection of Personal Data - Act on the Protection of Personal Data 1992
GMO	<ul style="list-style-type: none"> - The Law on Genetically Modified Organisms and Genetic Technologies 151/2002

Slovenia

Legal information system

<https://www.slov-lex.sk/web/en>

Data Protection	<ul style="list-style-type: none"> - Personal Data Protection Act (ZVOP-1)
GMOs	<ul style="list-style-type: none"> - The Act on the Management of Genetically Modified Organisms (2002)

Spain

Legal information system

<https://www.boe.es/buscar/legislacion.php> (Spanish)

Biobanking	<ul style="list-style-type: none">- Royal Decree 1716/2011, of 18th November, establishing the basic requirements for the authorization and operation of biobanks for biomedical research purposes and the treatment of biological samples of human origin.- Royal Decree 65/2006, of 30th January, establishing requirements for the import and export of biological samples.- Decree 234/2013, of 15th October, regulating authorization for the constitution and operation of biobanks for biomedical research purposes in Catalonia and the Catalan Biobanks Network.
Biomedical Research	<ul style="list-style-type: none">- Law 14/2007 of July 3rd on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V- Law 41/2002, of 14th November, basic law regulating patient autonomy, rights, and obligations regarding clinical information and documentation- Royal Decree 1720/2007, of December 21th, which approves the regulation implementing Organic Law 15/1999 of December 13th on the protection of personal data in any type of clinical research.
Clinical Trials	<ul style="list-style-type: none">- Royal Decree 223/2004, of February 6th, which regulates clinical drug trials.- ORDER SAS/3470/2009, of December 16th, which publishes guidelines on post-authorization observational studies for drugs for human use.
Data Protection	<ul style="list-style-type: none">- Organic Law 15/1999 of December 13th on the Protection of Personal Data- Law 3/2018, of 5th December, on the Protection of Personal Data and the guarantee of digital rights.
GMOs	<ul style="list-style-type: none">- Law 9/2003 Use of Genetically Modified Organisms
Human material	<ul style="list-style-type: none">- Law 14/2007 on Biomedical Research; Royal Decree 1301/2006 of November 10th Regarding the Use of Cells and Human Tissue- Royal Decree 2070/1999 of December 30th, Regarding Activities of Collection and Clinical Use of Human Organs for Organ Transplants and Tissues

	- Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples (2006)
Medical products	- LAW 29/2006, of July 26th, on guarantees and rational use of medicines and health products. - Royal Decree 1591/2009, of October 16th, that regulates medical devices.
Occupational Health and Safety	- Royal Decree 664/97 of December 5 th 1997 (Boletín oficial del Estado N. 124, 24/5/97, p. 16100-16111).

Sweden

Legal information system
<https://lagrummet.se/lagrummet/> (Swedish)

Animals	- Djurskyddsförordning - SFS 2019:66 - The Animal Welfare Act (L 1 Djurskyddslagen SFS 2018:1192) - Animal Welfare Ordinance SFS 1988:539
Data Protection	- Data Protection Act - Personal Data Act 1998
GMOs	- The Environmental bar (Code)
Occupational Health and Safety	- Swedish Work Environment Act (1977)

Non-EU countries

Australia

Legal information system
<https://www.legislation.gov.au/>

Animals	- Animal Welfare Act 2002 (use of animals for scientific purposes) - National guidelines for the use of animals for scientific purposes are provided in the Australian Code for the Care and Use of Animals for Scientific Purposes.
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	- The Scientific Use Code
Data Protection	- Privacy Act 1988
Bangladesh	
Data Protection	- Data Protection Act is currently being drafted
Burkina Faso	
Data Protection	- Law No 010-2004/AN on the Protection of Personal Data
Israel	
Animals	- Israeli Guidelines follow NIH/USA animal care and use protocols
Data Protection	- Privacy Protection Act No.5741/1981 and 5752/1992
Mali	
Data Protection	- Personal Data Protection Act - Law no. 2013-015 of May 21 st , 2013
Norway (EEA)	
Legal information system https://lovdata.no/info/information_in_english	
Animals	- Personal animal project licence: Norwegian Food Safety Authority - Mattilsynet (cf. Regulations on Animal Experiments §13 Planning and Conduct of Experiments. - Animal Welfare Act (Lov om dyrevelferd LOV-2009-06-19-97).
Biomedical Research	- Act on Medical and Health Research (2008): https://lovdata.no/dokument/NL/lov/2008-06-20-44?q=helseforskningsloven - Research Ethics Act (2017) - https://lovdata.no/dokument/NL/lov/2017-04-28-23?q=forskningsetikk
Data Protection	- The General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR) - Personal Data Act 2000

GMOs	- The Law on the production and use of genetically modified organisms (Genetic Technology Act) (1993)
Senegal	
Data Protection	- Law No. 2008-12 of January 25 th , 2008 on the Protection of Personal Data
Serbia	
Data Protection	- Data Protection Act - Law on Personal Data Protection N°97/08
South Africa	
Data Protection	- Protection of Personal Information Act 4 of 2013
Switzerland (EEAS)	
Legal information system Fedlex Federal law (admin.ch)	
Animals	- Animal Protection Act (AniPA) - Animal Protection Ordinance of 23 th April 2008 (AniPO)
Clinical Trials	- Clinical Trials Ordinance (ClinO, KlinV)
Data Protection	- Federal Act on Data Protection (FADP, DSG), 1992
GMOs	- The Federal Act on Non-human Gene Technology (2003)
Human Research	- Constitutional article on research on humans (118b BV) - Communication regarding the Federal Act on Research Involving Human Beings - Human Research Act (HRA, HFG) - Human Research Ordinance (HRO, HFV) - HRA Organisation Ordinance (OrgO-HRA, OV-HFG)

	<ul style="list-style-type: none"> - Federal Act on Human Genetic Testing (HGTA, GUMG) - Stem Cell Research Act (StRA, StFG)
Medical products	<ul style="list-style-type: none"> - Therapeutic Products Act (TPA, HMG) - Ordinance concerning Medical Devices (MepV)
Occupational Health and Safety	<ul style="list-style-type: none"> - Radiological Protection Act (RPA, StSG) - Radiological Protection Ordinance (RPO, StSV)
United Kingdom	
Legal information system https://www.legislation.gov.uk/	
Animals	<ul style="list-style-type: none"> - Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 - No. 3039 (ASPA, from 18th December 2012) – (Directive 2010/63/EU)
Data Protection	<ul style="list-style-type: none"> - Data Protection Act 1998 - Data Protection Act 2018
GMOs	<ul style="list-style-type: none"> - The Environmental Protection Act 1990
Human material	<ul style="list-style-type: none"> - Human Tissue Act published on November 15th, 2004 by the government of the United Kingdom
Inter-governmental organization (EMBL) - https://www.embl.org/	
Animals	<ul style="list-style-type: none"> - Internal Policy 65 - EMBL Policy on the Protection and Welfare of Animals Used for Scientific Purposes (in accordance with the standards applicable under the European Directive 2010/63/EU)
Biosafety	<ul style="list-style-type: none"> - For the classification of the used biological agents into the four risk groups, EMBL follows the directives and recommendations of international organizations such as the European Union, the Organization for Economic Cooperation and Development (OECD), and the World Health Organization (WHO) and aligns with the national law of the host country and the relevant national organizations, e. g., the Central Commission on Biological Safety (ZKBS) in Germany to facilitate the selection of appropriate safety measures.

Human material

- Internal Policy 53 – Use of Human Biological Material
 - Internal Policy 70 – Research Involving Human Embryonic Stem Cells and Tissues Derived
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