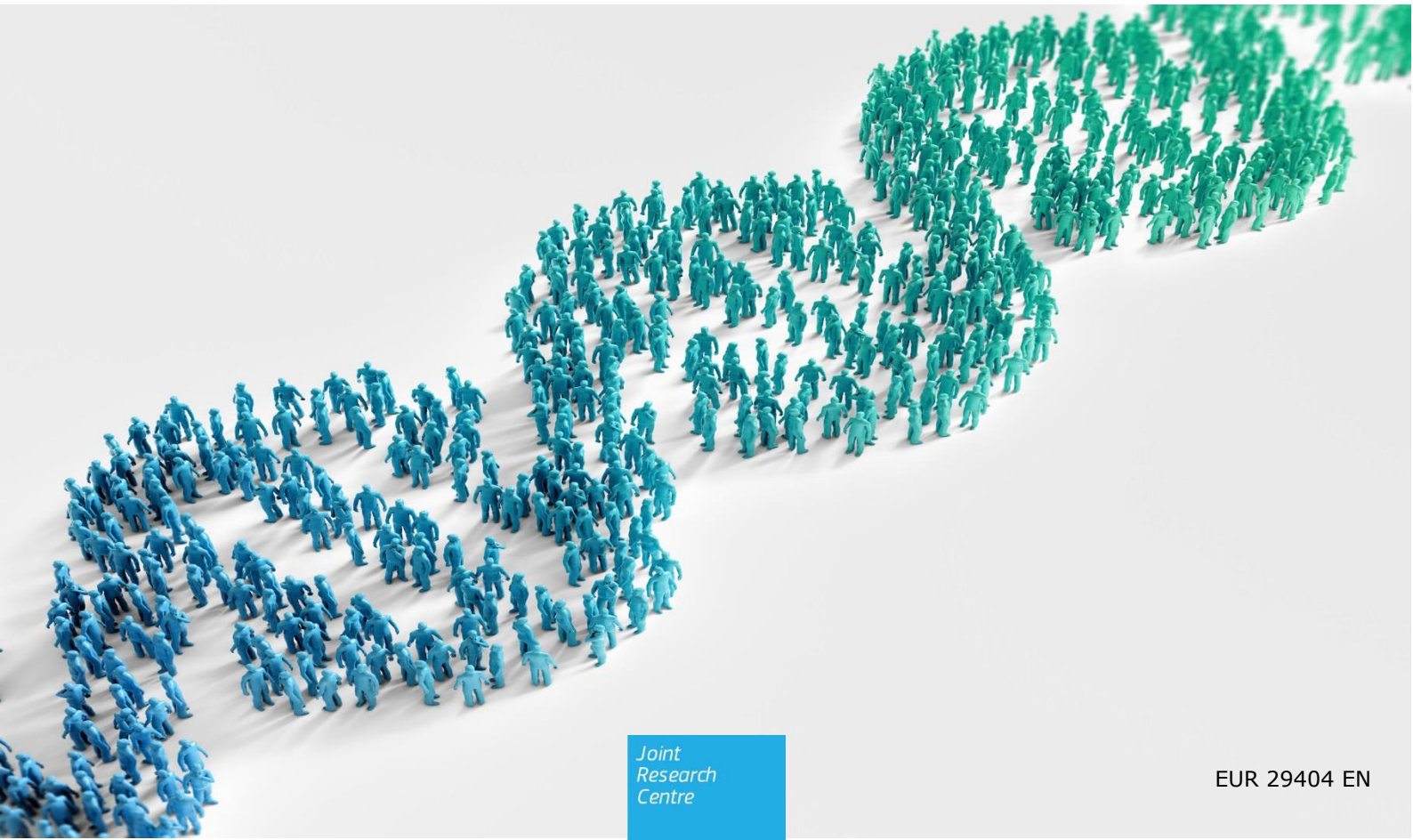
European Commission

JRC SCIENCE FOR POLICY REPORT

Overview of EU National Legislation on Genomics

JRC F7 - Knowledge Health and Consumer Safety

2018



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JRC Science Hub
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JRC113479

EUR 29404 EN

PDF ISBN 978-92-79-96740-5 ISSN 1831-9424 doi:10.2760/04463

Luxembourg: Publications Office of the European Union, 2018

How to cite this report: JRC F7 - Knowledge Health and Consumer Safety, *Overview of EU National Legislation on Genomics*, JRC Science for Policy Report, Luxembourg: European Commission, EUR 29404 EN, ISBN 978-92-79-96740-5, doi:10.2760/04463, PUBSY No. JRC113479

The genomic dimension of legislations across EU
This report presents a mapping, as complete as possible, of existing national legislations linked to genomics. It can be used as a baseline for the analyses of possible consequences for EU policies already in place, and to forecast policy gaps and eventual interventions.

Contents

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Acknowledgments

A special acknowledgment to Anna Bohacova for her excellent and comprehensive research that led to the finalising this report and to Dr. Ewan Birney (EMBL-EBI) for his valuable and competent comments.

Executive summary

With the advent of fast, high efficiency and low cost DNA sequencing techniques, the ability to study the human genome by reading the sequence of its DNA is growing exponentially, with a resulting tremendous impact on many fields of scientific research. The application of genomics inside routine healthcare is boosting preventive medicine practices and can lead to personalised treatments that can highly improve the healthcare services and patients' health, and in the same time provide a wealth of data for medical research.

In parallel, this has also led to the spread of commercial opportunities to provide consumers with the possibility of sequencing their genomes in a way which is both appealing and affordable. These commercial offers, however, do not always ensure the security of the generated data. In addition, the accuracy and reliability of the offered findings are not homogenous, as there are no standards to guarantee that the quality of the outputs satisfies minimum requirements - in fact, no agreements yet exist on the definition of these requirements.

In this frame, a comprehensive knowledge of what is present at the legislative level in the member states of the European Union (plus Switzerland, Iceland and Norway) regarding the regulatory oversight of genomics technologies is of fundamental importance to frame the status of existing European norms, to understand whether possible incompatibilities might arise between frameworks and to highlight eventual gaps.

Policy context

Various EU countries have ongoing or planned initiatives to sequence the genomes of large numbers of their citizens, as they launched, funded or are going to approve national personalised medicine programmes or initiatives based on genomics, to improve the diagnosis and prevention of human diseases, from (rare) monogenic syndromes to cancer. With the 'Declaration of Cooperation Towards access to at least 1 million sequenced genomes in the European Union by 2022', that was signed by 13 European countries, there is a strong commitment to share and combine this accumulated knowledge of genomic information. It is thus crucial, for this endeavour, to identify where there might be potential legislative obstacles in linking human genomics resources across countries, and to propose effective and efficient means to overcome them.

This report also feeds, more generally, into the ongoing activities within the JRC on eHealth and Big Data, both related to the implementation of the EC Digital Single Market strategy. Genomics will have a profound impact on personalised medicine, improving the screening, diagnosis and prevention of diseases, and may become an important component of a harmonised electronic health record for each EU citizen.

Key conclusions

This report highlights that:

1. The existing national legislations seem to focus on genes, their variations and hereditability in living organisms, while scientific interests and advancements, at the moment, have a more holistic view of the genomes of living organisms. Further reflections are needed to address this important gap in the legislative framework.

2. There is a number of areas that are differentially addressed in the regulatory frameworks of the different member states, such as human somatic and germ line modifications (through the application of gene and genome editing technologies),
3. Different legislative frameworks take into consideration the citizens'/patients' rights of having their personal genomic data characterised, used and shared.

An online interactive compendium should be produced and released, that would include all the legislative instruments retrieved and analysed for this report.

Main findings

This report presents a mapping, as complete as possible, of all existing (in force, and coming into force) national legislations regarding topics linked to genomics. The analysis of the content of the retrieved legislations highlighted as main common regulated areas provisions on GMOs, genetics in general, embryo research, criminal legislation, patents, data protection, discrimination, and genetics applied to employment, insurances and inheritance processes.

The mapping of the available legislation at the national level, summarised and analysed in this report, can be used as a baseline for the analyses of possible consequences for EU policies already in place, and to forecast policy gaps and eventual interventions.

Related and future JRC work

The first immediate next step will be the implementation of an online interactive compendium of all the retrieved legislative instruments, intended for public use.

Moreover the content of the report, as a deliverable the Omics in Society transversal action, can be of high interest for JRC Units dealing with ethics, cybersecurity, data privacy & protection, environment, law in general, and for other DGs of the European Commission (e.g.: RTD, SANTE, CONNECT, HOME, GROW, ENV).

Quick guide

The aim of this report is to provide an overview, as complete as possible, of the current legislations within the European Union member states, as well as Switzerland, Iceland and Norway, applying to Genomics.

The search for the legislative material has been performed through dedicated websites (both governmental and private) in each country that collect the national legislations. Whenever possible, the search functions of the websites have been used to retrieve the documentation. When this was not possible, other means to identify the correct documents had to be applied, on a case-by-case basis. Whenever possible, the English version of the documents (both official and non-official) has been preferred. Where no English translation was available, legislations were retrieved in their original language and then translated (using, if needed, the European Commission translation services).

Based on the material retrieved, a comprehensive analysis of the content was performed, highlighting communalities, as well as gaps, discrepancies and potential controversies.

1 Introduction

The aim of this report is to provide an overview, as complete as possible, of the current legislations within the European Union member states, as well as Switzerland, Iceland and Norway, applying to genomics, highlighting communalities as well as gaps, discrepancies and potential controversies. The report first highlights general trends in the types of legislation in place and the topics they cover. The second part of the report summarises key findings from each of the 31 jurisdictions covered. These summaries outline the scope of local law and highlight obvious omissions or outliers. A description of the methods employed in producing the accompanying individual country reports is also included.

According to the WHO definitions, "*Genetics is the study of heredity*", while "*Genomics is defined as the study of genes and their functions, and related techniques*". According to this definition, "*the main difference between genomics and genetics is that genetics scrutinizes the functioning and composition of the single gene whereas genomics addresses all genes and their inter relationships in order to identify their combined influence on the growth and development of the organism*" ([1]). According to the European Bioinformatics Institute (EMBL-EBI) "*Genomics is the study of whole genomes of organisms, and incorporates elements from genetics and it differs from 'classical genetics' in that it considers an organism's full complement of hereditary material, rather than one gene or one gene product at a time.*" ([2]).

Genomics come with two main topics that need to be addressed from a legal point of view: the production/handling of genomic information, and the use of new genomic technologies that are developed and use this information. For example, the application of genomic sequencing technology in a number of contexts continues to grow, ranging from the detection of crime to the identification of the causes of disease. Linked to the latter, there has been an increasing interest around the use of CRISPR-Cas9 DNA editing technologies, which can be used to edit the genome of any living organism, enabling precise cutting and pasting of DNA by specialized proteins. The potential uses of genomic information and technologies raises a number of significant social and ethical dilemmas, particularly on when, and how, these uses should be regulated.

([1]) WHO definitions of genetics and genomics: http://www.who.int/genomics/geneticsVSgenomics/en/

([2]) What is genomics? https://www.ebi.ac.uk/training/online/course/genomics-introduction-ebi-resources/what-genomics

2 General trends

2.1 Outlier Jurisdictions

The depth of regulation relevant to genetics varies starkly across the 31 analysed jurisdictions. Some have only a few tangentially related laws relating to genetics whilst others have a more comprehensive regulatory framework. According to our findings, the most comprehensive coverage of issues relating to genetics, and embryonic research is probably to be found in Switzerland. Swiss legislation provides a good example of a truly wide-ranging engagement with genetics, encompassing the Swiss Federal Act on Research Involving Embryonic Stem Cells (2003) and Federal Act on Human Genetic Testing (2004) and the Federal Act on Research Involving Human Beings (2011).

The other jurisdictions which have a comprehensive coverage of issues are: Norway, Lithuania, Latvia, Portugal, Estonia and Hungary. These jurisdictions have enacted bespoke genetic research laws, which engage deeply with the issues of genetic research, embryo research and genetic testing. The laws specify the time limitations on how long an embryo can be used in research and provide for prohibitions on germ-line alterations.

Jurisdictions which have only few legislative instruments relating to genetics, and the instruments enacted focus mainly on the environment and Genetically Modified Organisms ('GMO'), are: Bulgaria, Czech Republic, Slovakia, Greece, Ireland and Poland.

2.2 Genetically Modified Organisms

The most heavily legislated area in relation to genetics in the European Union (and Norway, Iceland and Switzerland) appears to be the use of GMOs in agriculture, foods and consumer products. Almost all 31 jurisdictions have passed comprehensive legislation which covers the licensing for GMOs, their handling and safety requirements. The legislative instruments identified throughout the course of this review, appear substantially the same and derive from the following European instruments: Directive 2001/18/EC on the deliberate release of GMOs into the environment; Regulation (EC) 1829/2003 on genetically modified food and feed; Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory; Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms; Directive 2009/41/EC on contained use of genetically modified micro-organisms; and Regulation (EC) 1946/2003 on transboundary movements of GMOs. The Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms was published on 9 March 2018 and comes into effect in September 2018.

The legislative provisions mirror the EU legislation and are divided into provisions for the contained use of GMOs, deliberate release of GMOs and placing of GMOs on the market. Most jurisdictions appear to have essentially the same legislation with respect to GMOs and require almost identical safety procedures. All surveyed jurisdictions (with the exception of Greece, where no relevant statute could be located), require persons to obtain a permit to use GMOs, the application process for such permits is largely the same in all the relevant countries. One difference is that some jurisdictions have promulgated

the GMO rules via primary legislation, whilst others through secondary legislation, as is the case for example with the UK, where most of the detail is contained in regulations; compared with say Cyprus where the detailed provisions on handling, licensing and use of GMOs are contained in primary legislative acts.

See the table below for a summary of each country and the key legislative instruments relating to GMOs.

Table 1. Summary of key legislative instruments relating to GMOs.

COUNTRY	LAW
Austria	The Gene Technology Act
Belgium	Royal Decree regulating the deliberate release into the environment and the placing on the market of genetically modified organisms or products containing GMOs (2004)
Bulgaria	The Law on Genetically Modified Organisms (2005)
Croatia	Act on Genetically Modified Organisms (2005)
Cyprus	Genetically Modified Organisms (Release into the Environment) Law of 2003 (160(I)/2003)
	Genetically Modified Organisms (Limited and Contained Use) Law of 2004 (15(I)/2004)
Czech Republic	Law N. 78/2004
Denmark	The Environment and Genetic Engineering Act No.9 of 4/1/2017
Estonia	The Contained Use of Genetically Modified Micro-organisms Act (2001)
	Release into Environment of Genetically Modified Organisms Act (2004)
Finland	The Gene Technology Act 17.3.1995/377
France	The Environmental Code
Germany	The Genetic Engineering Act (1993)
Greece	N/A
Hungary	The XXVII Law on Genetic Engineering (1998)
Iceland	The Act on GMOs (1996)
Ireland	The Environmental Protection Agency Act 1992
Italy	The Environmental rules – Legislative Decree of 3 April 2006, no 152
Latvia	The Law on Circulation of Genetically Modified Organisms (2007)

Lithuania	The Law on Genetically Modified Organisms (2001)
Luxembourg	The Law of 13 January 1997 on the Control of the Use and Dissemination of Genetically Modified Organisms
Malta	The Contained Use of Genetically Modified Micro-Organisms Regulations (2008)
	the Deliberate Release into the Environment of Genetically Modified Organisms Regulations (2010)
Norway	The Law on the production and use of genetically modified organisms etc. (Genetic Technology Act) (1993)
Poland	Act of 22 June 2001 on Microorganisms and genetically modified organisms
Portugal	The Law no 55/2015 of 17 April on the Confined Use of Genetically Modified Microorganisms and Organisms
Romania	Law no. 214 of 19 April 2002 for the approval of the Government Ordinance no. 49/2000
	Law no. 3 of 9 January 2008 for the approval of Government Emergency Ordinance no. 44/2007
	Law no. 247 of 30 June 2009 for the approval of Government Emergency Ordinance no. 43/2007
Slovakia	The Law on Genetically Modified Organisms and Genetic Technologies 151/2002
Slovenia	The Act on the Management of Genetically Modified Organisms (2002)
Spain	Law 9/2003 Use of Genetically Modified Organisms
Sweden	The Environmental bar (Code)
Switzerland	The Federal Act on Non-human Gene Technology (2003)
United Kingdom	The Environmental Protection Act 1990

2.3 Genetics in general

Many jurisdictions expressly forbid genetic modification of the human germ line, but some expressly allow modifications for the purposes of prevention, diagnosis or treatment as long as the intent is not to modify the germ line. Such provisions arguably open the door to utilising the potential beneficial somatic gene therapies arising out of applications of technologies such as CRISPR-Cas9. An example of such legislation is the Lithuanian Law on Ethics in Biomedical Research (2002), which provides that human biomedical studies which modify the human genome may only be carried out for the

purposes of prevention, diagnosis or treatment and only in cases where they are not intended to modify the progeny genome (the germ line).

A number of jurisdictions address the modification of the human germ line, which is usually prohibited when mentioned. The majority of jurisdictions, however do not appear to have specific prohibition on germ line alterations in humans. It is worth noting that essentially all 31 surveyed countries prohibit patents for germline alteration processes, which in itself may have a dampening effect on the use of any such processes, even in the absence of a specific legislative prohibition.

See below for a list of countries which address germ line alterations in some way. Note that many of these statutes are specifically targeted at embryo research.

Table 2. Summary of key legislative instruments relating to germ line alterations.

COUNTRY	LAW	NOTES
Austria	The Gene Technology Act	The Act allows for the use of genetic analysis in medical context, to detect diseases which are based on germ line mutation, especially in cases where there is scope for prevention of a disease occurring in the future.
Croatia	The Law on the Protection of Patient's Rights (2004)	The law specifies that interventions directed at changing the human genome can only be undertaken for preventative or therapeutic purposes and no interventions are allowed with the view to changing the patient's germ line.
Germany	The Embryo Protection Act (1990) No 69/1990	The Act in Article 5 strictly prohibits the alteration of the human germ line and provides that any breaches of the provision are punishable by up to 5 years in prison.
Lithuania	The Law on Artificial Fertilisation (2014)	The law prohibits the use of IVF as a means of modifying the identity of the germ line of a person or their offspring.
	The Law on Ethics in Biomedical Research (2002)	The law provides further that human cloning is prohibited; and biomedical studies which modify the human genome may only be carried out for the purposes of prevention, diagnosis or treatment and only in cases where they are not intended to modify the progeny genome (the germ line).
Malta	The Embryo Protection Act (2013)	Section 13 specifies that it is a criminal offence punishable by imprisonment and a substantial fine to alter in an artificial way the genetic information of a human germ line; it is also an offence to knowingly use

		such a cell.
Netherlands	The Law on Medical Research on Humans of 26 February 1998	The law forbids experimentations on humans in a way that changes the germ line of humans.
Portugal	The Law no 12/2015 of 26 January on Personal Genetic Information and Health Information	The Law prohibits the alteration of the human germ line.
Slovenia	Medicines Law (2014)	The law specifies that no clinical trials can be conducted where the drug/treatment would change the germ line of the patient.
Switzerland	The Federal Act on Research Involving Embryonic Stem Cells (2003)	The Act prohibits modification of genetic material in a germ cell, the derivation of embryonic stem cells from an embryo that has undergone germ line modification, or any use of such cells.
United Kingdom	The Human Fertilisation and Embryology Act 1990	The Act regulates through licences and third party agreements the storage, testing, processing and distribution of germ cells that are otherwise forbidden.

2.4 Embryo Research

The most common limit on embryo research in the jurisdictions where specific legislation could be located is that it is prohibited to cultivate and use embryos for research purposes for more than 14 days outside of the body or until the primitive streak has developed. Common is also some kind of a committee or an ethics body which must give permission for a research project to commence. An example of such a body is the Human Fertilisation and Embryology Authority in the UK.

Several jurisdictions have reasonably similar provisions on using embryos for research, such as the Icelandic Law on Artificial Fertilisation and the Use of Human Embryos and Embryos for Stem Cell Research (1996). This provides that embryos may be used for research in certain circumstances when they are not intended for in vitro fertilisation (IVF) and the research would yield useful scientific and medical knowledge, but all projects must be permitted by the Bioethics Committee. It must also be shown that there is no other way to conduct the research. It is prohibited to cultivate or produce embryos solely for research purposes and to retain embryos for more than 14 days outside the body, or once the primitive streak has developed. It is also prohibited to perform nuclear transfer for reproductive purposes (cloning) and transplant human embryos into animals. Similar provisions are in place in the UK, France, Sweden, Switzerland, Lithuania and Latvia.

The statutes are often primarily targeted at regulation of IVF and place limits on genetic alterations of embryos used for artificial fertilisation purposes. Note that most of the 31 jurisdictions' patents statutes provide for prohibitions of patents for commercial uses of embryos. For details see the 'patent' section below.

See below for a list of countries, which have specific provisions on embryo research relating to genetics, and brief description of the main points from the relevant legislative instruments.

Table 3. Summary of key legislative instruments relating to embryo research.

COUNTRY	LAW	NOTES
Belgium	In vitro Research on Embryos Act of 11 May 2003	The law permits research on embryos within the first 14 days of fertilization. The law specifies that any such research must be targeted at obtaining valuable knowledge relevant to health. The Law prohibits productions of embryos specifically for research and provides for how can permits for embryonic research be obtained.
Croatia	The Act on Assisted Reproduction (2012)	The Act provides for rules on donating eggs and sperm as well as embryos and the allowed use of these. It prohibits sex selection of a foetus, unless it is to prevent a sex-linked condition, and research on embryos and their alteration is generally prohibited.
Estonia	The Artificial Insemination and Embryo Protection Act (1997)	The Act prohibits the sex selection of embryos in IVF procedures except where there is a high probability of occurrence of a genetic disease linked to the sex chromosome. It is also prohibited to clone embryos or fuse the genetic information of embryos in order to create a cell fusion, if one of the embryos is a human embryo.
Finland	The Penal Code	The Code provides that it is an offence to clone a human, altering and generating human germ cells and animal genetic material and the generation of a human by combining embryos. These offences are punishable by imprisonment of up to 2 years.
France	Law on Bioethics	The Act provides that research on human embryos, embryonic stem cells and stem cell lines is generally prohibited. However, such research can be permitted if the scientific relevance of the research project is established, when the research is likely to allow major medical progress and the research cannot be performed any other way without the use of human embryos, embryonic stem cells or stem cell lines. Any such projects must be authorised by the Biomedicine Agency and adhere to the ethical codes promulgated by the Agency. The Article also specifies which embryos may be used for such research.
Germany	The Embryo Protection Act (1990)	The Act prohibits selection of embryos on the basis of sex except for cases where it is to prevent Duchenne muscular dystrophy or a similarly serious sex-linked genetic disease; prohibits the genetic examination of the cells of an embryo in vitro prior to intrauterine

		transfer. The Act in Article 6 further provides that it is prohibited to clone an embryo and place any such embryo into the womb. In Article 7 the Act prohibits creation of chimera and hybrid formation and placing any such creations into a womb.
Greece	The Law 3305 Applying Medical Assisted Reproduction	The law governs research on cells and embryos which are not destined for pregnancy. Research can be carried out to expand human knowledge and to improve diagnosis and treatment methods for infertility as well as contraception, to develop and control treatment techniques for genetic diseases and abnormalities and to study the biology of embryonic cells and their possible therapeutic uses. A licence is necessary for any such research.
Iceland	The Law on Artificial Fertilisation and the Use of Human Embryos and Embryos for Stem Cell Research (1996)	Embryos may be used for research in certain circumstances when they are not intended for IVF and the research would yield useful scientific and medical knowledge, but all projects must be permitted by the Bioethics Committee. It must also be shown that there is no other way to conduct the research. It is prohibited to cultivate or produce embryos solely for research purposes and have embryos for more than 14 days outside the body or once the primitive streak has developed. It is also prohibited to perform nuclear transfer for reproductive purposes (cloning) and transplant human embryos into animals.
Italy	The Law of 19th February 2004 n 40 – Rules on Medically Assisted Procreation	As per Article 13, experimentation on embryos is forbidden, any form of eugenic selections of embryos or gametes through any techniques aimed at altering the genetic information of the embryo or gamete or 'designing' the genetic characteristics of an embryo is also forbidden. Exceptions are allowed for disease-prevention.
Lithuania	The Law on Ethics in Biomedical Research (2002)	The law provides that where human embryos or foetuses are used in biomedical studies, only those where the benefits are expected to outweigh the risks for the human embryo and human foetus are allowed.
Malta	The Embryo Protection Act (2013)	The Act prohibits the selection of embryos based on the presence or absence of a sex-chromosome, except where it is done to prevent the occurrence of a sex-linked genetic illness. It is an offence to unite embryos with different genetic material to a cell conglomerate using at least one human embryo. It is also an offence to join a human embryo with a cell that contains genetic information different from the embryo cells and induces them to develop further.
Netherlands	The Embryo Law of 20 June 2002	The Law forbids all actions involving germ cells or embryos with a view to the birth of a genetically identical human being, or to deliberately modify the genetic material of the nucleus of human germ cells

		which might establish a pregnancy.
Norway	The Act on Human Medicine Use of Biotechnology, etc. (Biotechnology Act) (2003)	The law regulates when fertilised eggs may be used for research; prohibits research that causes genetic changes which may be inherited in humans; and prohibits production of embryos by cloning.
Portugal	The Law no 32/2006 of 26 July on Medically Assisted Procreation	It is forbidden to sex-select embryos other than for the purpose of preventing a serious sex-linked genetic disease. It is forbidden to use pre-implantation genetic diagnosis for multifactorial diseases where the predictive value of the test is very low. Use of embryos in research is only allowed when the research is expected to be of great benefit to humanity. There are limits on what embryos are allowed to be used for research; one source of embryos is embryos which have been identified in pre-implantation genetic diagnosis as having a severe genetic abnormality.
Romania	Civil Code of 17 July 2009 (Law 287/2009)	The Code prohibits the choosing of the sex of an embryo unless the reason for the choice is to avoid or prevent a genetic disease
Sweden	The Act on Biobanks in Healthcare, etc. 2002:297	The Act provides that research on embryos can be performed if the ethics committee approves the project and the embryo can be used for up to 14 days post fertilisation and limits the time of freezing of eggs/embryos to 5 years.
Switzerland	Federal Constitution of Switzerland	It provides for the following: all forms of cloning and interference with the genetic material of human reproductive cells and embryos is unlawful; non-human reproductive and genetic material may neither be introduced into nor combined with human reproductive material; IVF may only be used if there is an infertility issue or a risk of transmitting a serious illness and donation of embryos is unlawful.
	The Federal Act on Medically Assisted Reproduction (1998)	The Law restricts analysis of genetic material of reproductive cells and embryos in vitro is to cases where selection of sex or other characteristics is necessary because of a risk that the presence of certain genes will inhibit the developmental capacity of the embryo and when there is no other way of avoiding a serious disease. The Act also regulates how and when reproductive cells can be preserved, namely with the consent of the donor and for a maximum of 5 years and limits the number of embryos developed in the IVF context per woman to a maximum number of twelve. The Act creates an offence for acts whereby a person who in the course of a reproductive technique analyses the

		genetic material of reproductive cells or embryos in vitro and selects them according to their sex or according to other characteristics, without aiming to overcome infertility or avoid the transmission of the predisposition to a serious disease to the offspring shall be liable to a custodial sentence not exceeding three years or to a monetary penalty
	The Federal Act on Research Involving Embryonic Stem Cells (2003)	The Act prohibits a number of acts including the creation of an embryo for research purposes, the modification of the genetic material in a germ cell, the derivation of embryonic stem cells from an embryo that has undergone germ line modification, or the use of such cells; it is also prohibited to create a clone, chimer or a hybrid.
United Kingdom	The Human Fertilisation and Embryology Act 1990	The Act prohibits a number of acts including the creation of an embryo, except when holding a licence issued by the Authority. Generally speaking, without authorisation, there cannot be any genetic alterations of eggs and sperm and no person shall use modified germ cells to provide fertility services. The Act also provides for prohibitions in connection to genetic material of non-human origin, namely that (1) no person shall place in a woman a human admixed embryo, other embryo that is not a human embryo or gametes that are not human gametes; (2) no person shall mix human gametes with animal gametes, bring about the creation of a human admixed embryo or keep or use such an embryo; (3) licences cannot authorise the keeping or using of a human admixed embryo after the appearance of the primitive streak or the end of 14 days beginning with the day on which the process of creating the embryo began and (4) licences cannot authorise placing human admixed embryos in an animal or keeping or using a human admixed embryo in any circumstances in which regulations prohibit it. Hence there is a hard limit of 14 days for embryonic research from the time of fertilisation.

2.5 Criminal Legislation

Numerous jurisdictions provide for gene-related offences. The offences are related to cloning, modifying germ line of humans or dispersing GMOs without appropriate authorisations. The specific offences vary from country to country to a large degree, but there is a common thread of offences related to GMOs and cloning.

For example, the Spanish Penal Code creates several offences relating to genetic information modification. Genetic modification in humans is prohibited for all purposes except for those where the aim is to eliminate or reduce defect or serious disease. Or, the Italian Law of 19th February 2004 n40 – Rules on Medically Assisted Procreation prohibits behaviour which may lead to cloning a person. This act is punishable by 10-20 years in prison and a substantial monetary penalty.

Most jurisdictions also cover the collection, handling and storage of DNA in criminal investigations and/or proceedings. The idea is generally broadly the same; the law provides that subjects must often consent, but carves out when consent is not necessary and regulates the way the DNA is collected, stored and analysed as well as destroyed. An example is the Portuguese Law no 5/2008 of 12 February on the DNA Profile Database – Civil and Criminal Identification regulates and establishes DNA profile database for both criminal and civil litigation.

A number of jurisdictions provides for specific DNA databases used in their criminal justice systems. These are usually designed to store DNA profiles for identification of suspects and convicts in criminal investigations and/or proceedings.

See below for details of criminal legislation in each jurisdiction relating to genetics. The table provides details of all relevant legislative instruments in the criminal context and highlights the existence of DNA databases, where these have been found to be in place.

Table 4. Summary of details of criminal legislations relating to genetics.

COUNTRY	LAW	ACCESS / NOTES
Austria	Criminal Procedure Code	The Act limits the use of genetic data collected from suspects and convicts to the purpose.
	Aliens Police Act 100/2015	The Act provides for public authority powers in some very limited circumstances to check a person's DNA to confirm their identity, especially to prove a familial relationship in cases of family migration.
	Border Control Act 435/1996	The Act provides for public authority powers in some very limited circumstances to check a person's DNA to confirm their identity, especially to prove a familial relationship in cases of family migration.
	Citizenship Law 311/1985	The Act provides for public authority powers in some very limited circumstances to check a person's DNA to confirm their identity, especially to prove a familial relationship in cases of family migration.
Croatia	The Criminal Procedure Code	The Code provides for how DNA is to be handled during and after criminal investigations and which persons have the authority to access the genetic data, when the data are to be destroyed and what consents are necessary from the subject of the investigation.
Czech Republic	Law N. 227/2006 (The Penal Code)	The Code specifies certain acts as offences; these include handling and using human genetic information in prohibited ways. These prohibited acts relate especially, to breaches of

		confidentiality.
Denmark	The Law on processing of personal data by law enforcement authorities No. 410 of 27/4/2017	The Law regulates how police and associated authorities can process personal data.
	The Act on Establishment of a central DNA profile register No. 434 of 31/5/2000	The Act establishes a central DNA profile register.
Estonia	The Forensic Examination Act (2001)	The Act establishes a National DNA Database for storing and collecting DNA of prisoners and suspects in criminal matters.
	The Imprisonment Act (2000)	The Act provides for the way prisoners' DNA samples are to be handled.
Finland	The Penal Code	The Code specifies offences related to genetics. It is an offence to clone human, altering and generating human germ cells and animal genetic material and the generation of a human by combining embryos. These offences are punishable by imprisonment of up to 2 years. It is also prohibited to intentionally spread GMOs in violation of the Gene Technology Act and export GMOs without a licence.
	The Coercive Measures Act	The Act provides for situations when DNA can be collected from criminal suspects and specifies how the samples and any resulting data are to be handled, stored and destroyed.
France	The Penal Code	The Code outlines numerous offences related to genetics when a person breaches provisions relating to examination of a person's genetic characteristics and breaches provisions of biomedical ethics. The Code also provides and establishes the national automated DNA file and provides how it shall be operated and who has access to the information thereby contained.
Germany	The Code of Criminal Procedure (1987)	The Code provides for how DNA is to be used in the context of criminal investigations, it limits the scope of genetic analysis which can be performed on samples and specifies how DNA samples can be collected and when consent for collection is not necessary.
Hungary	The LXVI Law on the Registration of Citizen's Personal Data and Address	The Law provides for DNA procedures in criminal context It specifies when DNA samples can be taken from suspects or convicted persons, how and when DNA samples must be registered and

	(1992)	how DNA can be shared with other EU countries. The Law also provides for how long DNA is kept in the database and how it is to be stored.
Iceland	The Law on Genetic Register of Police (2001)	It establishes the Icelandic DNA database for storing and comparing DNA of suspects and convicts. The Law specifies when and how DNA can be collected, when must it be destroyed, who can have access to the information; and provides that the Data Protection Authority shall ensure proper administration of the database and protect the privacy of the individuals whose information is contained in the database.
Ireland	Criminal Justice (Forensic Evidence and DNA Database System) 2014 Act	The Act establishes the DNA database, as well as the framework for when DNA samples can be taken from suspects and the procedures for collection, storage and handling of the samples and any resulting data.
Latvia	The Law on Development and Use of National DNA Database (2004)	The law establishes a national DNA database to record criminal offences; the Law also regulates the exchange of the results of GNA genetic analysis with other States and international organisations.
Lithuania	The Police Law (2000)	The Law authorises relevant officials to take samples of genetic material without consent for comparative study and identification purposes
	The Law on the Approval, Entry into Effect and Implementation of Criminal Procedure (2002)	The Law provides when suspects' genetic information can be taken, despite the lack of consent of the suspect.
Luxembourg	The Penal Code	It provides for the use of DNA in the context of criminal proceedings. It specifies when DNA samples can be collected from suspects or convicts and the exact procedure of doing so. It provides for the protection of all DNA data collected and how the samples are to be stored and handled.
Malta	The Criminal Code (1854)	The Code specifies who can collect DNA in criminal proceedings and when DNA can be transmitted outside Malta
Netherlands	The Code of Criminal Procedure of 15 January 1921	The Code provides for when DNA samples can be taken with and without consent from suspects; and specifies the collection procedure, handling and analysis of all DNA samples in the context of a criminal investigation and/or proceeding.
	Law on DNA and Convicted Persons of	The Law provides further details on how DNA analysis is to be carried out in the context of a criminal proceeding and specifies when collections

	16 September 2004	of DNA samples are allowed.
Portugal	The Law no 5/2008 of 12 February on the DNA Profile Database – Civil and Criminal Identification	The Law regulates how the DNA data is to be stored and handled and what safety measures must be in place and for what purposes can DNA be collected.
Romania	Code of Criminal procedure of 1 July 2010 (Law 135/2010)	The Law outlines when genetic samples can be taken in the context of criminal proceedings and/or investigation
	The Law no. 76 of 8 April 2008 on the organisation and operation of the National System of Judicial Genetic Data	The Law establishes the National System of Judicial Genetic Data and sets out the conditions under which DNA samples can be taken from suspects and convicts; and how the data is to be processed and stored.
Slovakia	Criminal Law 300/2005	The Law prohibits the creation of a genetically identical human being to another one alive or dead. It is also an offence to breach the laws relating to GMOs and genetic technologies.
Slovenia	Law on Police Orders and Authorisations (2013)	The Law provides limits on police powers. It stipulates a principle of equal treatment prohibiting police offices to discriminate against anyone on the grounds of genetic heritage (Art 14).
Spain	Penal Code	The Code provides for when DNA samples can be taken for suspects and convicts; and outlines the procedures for collecting, storing and destroying DNA. The Code creates several offences relating to genetic information modification. Genetic modification in humans is prohibited for all purposes, except for those where the aim is to eliminate or reduce defect or serious disease. Breach of this provision carries a prison sentence. As per section 160, the use of genetic engineering to produce biological weapons is prohibited and punishable by imprisonment. It is prohibited to fertilise human eggs for any other purpose than for human reproduction; this provision carries a custodial sentence. The creation of genetically-identical humans (clones) is prohibited and will be punished by imprisonment.
United Kingdom	The Police and Criminal Evidence Act 1984	The Act regulates when DNA profiles can be included on the National DNA Database in the context of criminal investigations and/or proceedings. The Act specifies when DNA samples and profiles can be destroyed and provides that the National DNA Database Strategy Board must

		make arrangements for the database operations.

In the following jurisdiction, no relevant criminal provisions could be located: Belgium, Bulgaria, Cyprus, Greece, Italy, Norway, Poland, Sweden, Switzerland (the offences pertaining to embryo research and the like are contained in sections 'embryo research' and 'genetics in general'). Note that in most of these jurisdictions, it is very likely that the offences and provisions on criminal procedures relating to genetics are contained in secondary legislation, and as such, beyond the scope of this review. In other jurisdictions, for example Norway and Switzerland the offences are contained in the main Acts themselves, so the offences for mishandling GMOs are contained in the Act on GMOs etc.

2.6 Patents

The patent legislation across most of the 31 jurisdictions shows a large degree of uniformity due to the Directive 98/44/EC on the legal protection of biotechnological inventions. Most laws on this topic contain a near identical provision to, for example, section 1 of the Danish Patent Act No. 221 of 26/2/2017 which allows patents for biological material (including genes or gene sequences in some circumstances) and prohibits patents for methods of cloning humans, methods for modifying the human germline, use of embryos for industrial or commercial purposes and methods for modifying animal genetic identity which may cause disease unless there is a significant medical utility for humans or animals. An almost identical wording is found in most of the 31 jurisdictions' patent statutes.

One exception is Ireland which appears not to include any specific references to genes or embryos in its Patents Act 1992. Austria and Sweden include the phrase 'public order and morality' as grounds for refusing patentability of an invention; and Switzerland in its Federal Act on Patents for Inventions (1954) provides more detail in its legislation specifying processes for forming hybrid organisms by using human germ cells, human totipotent cells or human embryonic stem cells and the entities obtained thereby; processes of parthenogenesis by using human germinal material and the parthenogenetic entities obtained thereby as processes which are not patentable.

For further clarity see here the standard provisions, which are included in most of the laws listed in the table below. Here are the relevant contents of the Austrian Patent Law 259/1970. The law prohibits any invention to be patented if it is deemed to violate 'public order and morality', which covers a potentially wide and discretionary area of prohibition. The Law further specifies that methods for cloning human beings and altering the genetic identity of the germ line of a human are not patentable, nor is the commercial use of human embryos and methods of altering the genetic identity of animals which would cause undue suffering to animals without a justifiable benefit to animals or humans. The Patent Law further specifies that the mere discovery of a constituent of a human body, including the sequence or partial sequence of a gene is not patentable. The prohibitions contained in the Patent Law may bar commercial exploitation of some gene technologies and limit the financial incentives for research. These provisions are fairly standard, except for the inclusion of violation of 'public order and morality' as grounds for unpatentability of an invention, which only appears in some jurisdictions.

See below for a list of the relevant patent statutes. Note that most of these are near identical to the Danish and Austrian statutes described above, so no notes were needed.

Table 5. Summary of relevant patent statutes.

COUNTRY	LAW
Austria	The Patent Law 259/1970
Belgium	The Patent Law of March 28, 1984 (as amended on December 22, 2008)
Bulgaria	The Patent Law (1993)
Croatia	The Croatian Patent Law (2003)
Cyprus	The Patent Law of 1998 (16 (I)/1998)
Czech Republic	Law N. 206/2000 on the protection of biotechnological inventions
Denmark	The Patent Act No. 221 of 26/2/2017
Estonia	The Patents Act (1994)
Finland	The Patents Act 15.12.1967/550
France	Intellectual Property Code
Germany	The Patent Law (1980)
Greece	Greek IP laws
Hungary	XXXIII Law on Patents and Protection of Inventions (1995)
Iceland	The Patent Act (1991)
Ireland	The Patents Act 1992
Italy	Patent law (Royal Decree No. 1127 of June 29, 1939, as last amended by Legislative Decree No. 198 of March 19, 1996)
Latvia	The Patent Law (2007)
Lithuania	The Patent Law (1994)
Luxembourg	Law of 7 April Amending the Amended Law of 20 July 1992 Amending the Patent System
Malta	The Patents and Designs Act (2002)
Netherlands	The Patent Act of 15 December 1994
Norway	The Patent Act (1967)
Poland	The Act of 9 May 2007 about Amending the Act on Copyright and

	Related Rights and some other Laws
Portugal	The Industrial Property Code – Law no 36/2003 of 5 March
Romania	Law No. 64/1991 on Patents (as amended up to Law No. 83/2014)
Slovakia	The Patent Law 435/2001
Slovenia	Industrial Property Act (ZIL-1-UPB3) (as amended up to December 6, 2013)
Spain	Law 10/2002 of 29 April
Sweden	Patent Act 1967
Switzerland	Federal Act on Patents for Inventions (1954)
United Kingdom	The Patents Act 1977

2.7 Data Protection

Most jurisdictions have comprehensive and almost identical Data Protection Acts which either expressly or by implication include genetic data in a category of 'special or sensitive personal data', which is afforded higher privacy protections. Generally speaking consent of the subject must be sought to process the genetic data in any way. It should be noted that the General Data Protection Regulation ('GDPR'), which entered into force in May 2018, has had effect on many of the statutes discussed in this section. Many of the jurisdictions are still in the process of amending their legislative instruments or have very recently done so. For example, in Austria as of April 2018 there were several Bills and pending legislative proposals, which would place greater protections on genetic data in line with the GDPR. The key point is that genetic data must now be more heavily protected than was the case until recently across all the surveyed jurisdictions.

See the table below for details of legislation relating to data protection and genetics.

Table 6. Summary of relevant legislation on data protection and genetics.

COUNTRY	LAW	NOTES
Austria	Data Protection Act	The Act does not directly reference genetic data but includes in the definition of sensitive data (which is subject to greater protections), 'health data' and data capable of revealing some information about a person's health and racial or ethnic origin. Hence sensitive data would in many instances likely include genetic data.
Cyprus	The Personal Data Processing Act (Protection	The Act covers data protection of sensitive personal data, which does not specifically

	of Individuals) Law of 2001 (138(I)/2001)	include genetic information but does include health information and information relating to ethnicity and race, which could presumably include some genetic information.
Czech Republic	Law N. 101/2000	The law explicitly includes genetic data as sensitive personal information, thus subjecting genetic data to greater measures of protection. The Law further specifies the obligations on those storing or processing sensitive personal information.
Estonia	The Personal Data Protection Act (2007)	The Act covers the area of protection and handling of personal data, including genetic data. Genetic data are expressly included as sensitive personal data and are thus subject to greater protections provided by most of the sections 12 to 42 of the Act. There are strict limits on how sensitive personal data may be processed and there is an obligation to register all processing of sensitive personal data with the relevant Authority.
Hungary	XXI Law on the Protection of Human Genetic Data, on the Rules of Human Genetic Testing and Research and Operation of Biobanks (2008)	The Law aims to protect people's genetic information. It provides how genetic data is to be handled, when it can be used for research and how genetic analysis can be carried out and provides rules for biobanks.
Iceland	The Privacy Act (2000)	The Act specifies genetic information as sensitive personal information and hence all provisions governing the handling, storage and access to sensitive personal information govern genetic information and this information is afforded the highest level of protection by the law.
Ireland	The Data Protection Act 2018	The Act provides for the protection of personal data which includes genetic data and which is subject to a high protection level because it is specified as a special category of data.
Italy	The Code for the Protection of Personal Data (2003)	The Code includes genetics as personal data and provide how a person consents, must be informed and when notifications are necessary when the genetic data is being used. There is a special provision on the handling of genetic data of bone marrow donors.
Luxembourg	The Law of 2 August 2002 on the Protection of Individuals with regard to the Processing of Personal	The Law provides for security protections of genetic data classified as health data, which is subject to higher protection than other

	Data	kinds of data.
Portugal	The Law no 67/1998 of 26 October on Personal Data Protection Act	The Law regulates access to and handling of personal data the personal data includes genetic information. Genetic information is classified as sensitive personal information and special procedures must be employed when handling such data.
Slovakia	Law on the protection of personal data 18/2018	The Law includes genetic information in personal data and genetic data is thus afforded a higher level of protection; and persons must give their consent for their genetic information to be processed, as per section 16.
United Kingdom	The Data Protection Act 2018	The Act regulates the protection of personal data, which includes genetic information. The Act provides more stringent protections to sensitive processing, which includes the processing of genetic data. The Act also limits the processing of genetic data by insurance providers.

The jurisdictions, which are not included in the table above most likely do not directly mention genetics in the text of the statute and/or include data protection as regulations or secondary legislation, and as such, outside of the scope of this review.

2.8 Other

There are other notable instances of legislation covering genetics which are less common and provide interesting examples of jurisdictional diversity.

2.8.1 Employment and genetics

One example of genetic provisions within employment law is the Finnish prohibition on mandatory genetic testing of employees; neither are employers allowed to request results of any such test if the employee had previously undergone genetic testing as provided by the Finnish Act on Protection of Privacy in Working Life 13.8.2004/759. Similar provision is made in Article 19 of the German Genetic Testing Act.

2.8.2 Insurance and genetics

Some jurisdictions also address genetics in the insurance context. The German Genetic Testing Act, for example, provides in Article 18 that it is prohibited to require genetic data from a person in the health insurance context, but it is allowed in the contact of occupational disability and nursing care insurance. The Icelandic Law on Insurance Contracts (2004) similarly prohibits companies to use results of genetic testing and any associated risks of developing certain diseases to determine the insurance policy of clients; nor are companies allowed to request such information from people. The

Lithuanian Insurance Law (2003) in Article 117 also prohibits insurers to take into account or require any genetic data from insured persons.

2.8.3 Animals and genetics

A variety of animal-related laws touches on genetics. An example is the Slovakian Law against animal abuse 246/1992, which provides that experiments on animals are to be carried out on animals which are designated for that purpose and suited from a genetic perspective before any other animals. Another is the Dutch Law on Animal Testing of 12 January 1977, which provides when animal experiments end with regards to genetically modified animal lines. The Animal Law of 19 May 2011 forbids changing of genetic material of animals solely for the purpose of enhancing their sporting performance or entertainment in a manner that ignores the natural barriers of sexual reproduction and recombination. It is also prohibited to use biotechnological techniques on an animal or an animal embryo without a permit.

3 Country summaries

The present chapter presents the summaries of the key legislation of each of the 31 countries analysed.

Only the more relevant instruments and their aspects are discussed below. For a more comprehensive overview, which includes potentially less relevant legislative provisions, an on-line interactive compendium of all the retrieved legislative instruments, intended for public use will soon be established.

The scope of the analysis is limited to primary national legislation and does not extend to local regulations, decrees or other administrative or regional and local acts.

The search for the legislative material has been performed through national dedicated websites (both governmental and non-governmental) that collect the national legislation. Whenever possible, the search facilities of the websites have been used to retrieve the documentation. When this was not possible other means to identify the correct norms had to be identified, on a case by case basis, leading to less precise and exhaustive results.

Whenever possible, the English version of the documents (both official and non-official translations) has been preferred. Where no English translation was identified, legislations were achieved in original language and then translated, using different means, including the European Commission translation services of DG-Translation, when needed.

3.1 Austria

General Outline

Austria has a fairly comprehensive legislative regime relating to genetics, which covers areas of data protection, patents, criminal prosecution, genetically modified organisms as well as environmental protection. The legislation is broadly standard as compared across the European Union and the EEA; there are no significant outliers or omissions as compared to the rest of the block. The one notable exception is the inclusion of violation of 'public order and morality' as a ground for unpatentability of an invention which is only rarely repeated in patents legislation and the only comparable wording was found in the Swedish Patent Act.

Most relevant legislation: The most directly relevant legislative instruments are the Patent Law, the Gene Technology Act and the Data Protection Act.

Patents

The Patent Law (Patentgesetz 1970) prohibits any invention to be patented if it is deemed to violate 'public order and morality', which covers a potentially wide and discretionary area of prohibition ([3]). The Law further specifies that methods for cloning human beings and altering the genetic identity of the germ line of a human are not patentable, nor is the commercial use of human embryos and methods of altering the genetic identity of animals which would cause undue suffering to animals without a justifiable benefit to animals or humans.([4]) The Patent Law further specifies that the mere discovery of a constituent of a human body, including the sequence or partial sequence of a gene is not patentable. The prohibitions contained in the Patent Law may bar commercial exploitation of some gene technologies and limit the financial incentives

([3]) Patent Law 259/1970, art 2
([4]) Patent Law 259/1970, art 2

for research. These provisions seem fairly standard, except for the inclusion of violation of 'public order and morality' as grounds for unpatentability of an invention.

Criminal context

Austria has a number of laws which govern the handling of genetic material in the criminal context. The Criminal Procedure Code limits the use of genetic data collected from suspects and convicts to the purpose for which the data was initially collected and provides strict provisions as to when data should be deleted ([5]). The same law also specifies how a DNA analysis is to be carried out. It provides that DNA is included as 'sensitive data' and specifies how the data should be handled. The Security Police Act 566/1991 provides how DNA is to be used in the identification of persons. The police power is limited to utilising DNA to cases where the person is suspected of having committed a criminal offence, which carries a sentence of at least one year of imprisonment ([6]).

The Aliens Police Act 100/2015, the Border Control Act 435/1996 and the Citizenship Law 311/1985 provide for public authority powers in some very limited circumstances to check a person's DNA to confirm their identity, especially to prove a familial relationship in cases of family migration ([7]).

GMOs and genetic technology

The Gene Technology Act implements the Council Directive 98/91/EC among others and regulates the use of gene technologies and GMO use and licensing. Importantly, Article 65 outlines the limited reasons for which genetic analysis for medical purposes can be carried out. The enumerated purposes are to identify existing diseases and for the preparation to use gene therapy on the patient where the therapy is based on specific genetic markers. Genetic analysis can also be used to detect diseases which are based on a germ line mutation and to establish a predisposition for a disease, especially to evaluate the likelihood of a genetic disease occurring in the future where there is scope for prevention. The Act also specifies when genetic analysis in humans can be used for scientific purposes and training ([8]), and limits the use of gene data beyond the original purpose of its collection. The Act further provides details of the qualifications and procedures whilst handling genetic data and situations where genetic information can be revealed to family members. The Act also provides for when gene therapy is allowed and what must be satisfied before it can be administered to patients ([9]).

The Animal Rights Law specifies when the germ line of animals may be changed via scientific experiments and when experimentation has to end ([10]).

Lastly, the Genetic Engineering and Cultivation Prohibition Law 93/2015 aims to prevent undesirable effects of GMOs, and establishes the Advisory Council for the Coordination of Genetic Engineering, which is tasked with exchanging information and cooperating with other similar bodies on European and regional developments in the authorisation, monitoring and application of genetically modified organisms ([11]).

([5]) Criminal Procedure Code 1975, art 75
([6]) Aliens Police Act 100/ 2005
([7]) Aliens Police Act 100/2005; Border Control Act 435/1996
([8]) Gene Technology Act 510/1994, art 66
([9]) Gene Technology Act 510/1994, arts 72, 74, 75
([10]) Animal Rights Law Amendment Act – TVRAG, arts 2, 11
([11]) Genetic Engineering Cultivation Prohibition Law 93/2015, art 1

Data protection

Austria's Data Protection Act does not directly reference genetic data but includes in the definition of sensitive data (which is subject to greater protections), 'health data' and data capable of revealing some information about a person's health and racial or ethnic origin ([12]). Hence sensitive data would in many instances likely include genetic data which should therefore be subject to greater protections under the Data Protection Act. Note that as of April 2018 there were several Bills and pending legislative proposals which would place greater protections on genetic data in line with the GDPR. The current Act provides for special regulation of use of sensitive data in scientific and statistical investigations which could impact genetics research ([13]).

Environment and food safety

The Environmental Information Act 495/1993 provides for free access to information regarding the environment, which includes access to information relating to genetically modified organisms ([14]). The freely accessible information appears to cover mainly the location and use of genetically modified organisms and disclosure of any potential risks.

The Food Safety and Consumer Protection Law 13/2006 provides for measures for tracing and labelling of GMO foods and protection of consumers against any detrimental effects of GMOs ([15]).

3.2 Belgium

General Outline

The Belgian laws which were located provide a relevant coverage of the issues surrounding genetics research. The most significant legislation is the Law of 11 May 2003 on research on in vitro embryos, which outlines when research on embryos is allowed.

Most relevant legislation: Law of 11 May 2003 on research on in vitro embryos

Embryo research

In Belgium, stem cell research is regulated by the "In vitro Research on Embryos" Act of 11 May 2003 ([16]). Consequently, in Belgium, it is legally permitted to conduct research on embryos within 14 days of fertilization. The condition is that the research pursues therapeutic goals and knowledge about the prevention or treatment of diseases. Also gaining new knowledge in the areas of fertility, sterility and organ tissue transplantation are reasons for research on embryos in vitro if no other research methods promise qualitatively equivalent results. The production of embryos specifically for research purposes is generally prohibited, but is permitted if the existing "surplus" embryos do not meet the needs of the research project. The law further provides that reproductive cloning is prohibited, and all research projects must be submitted to the local ethics committee. The use of embryos for commercial purposes is likewise prohibited, as is the

([12]) Data Protection Act 2000, art 4
([13]) Data Protection Act 2000, art 46
([14]) Environmental Information Act 495/1993, art 4
([15]) Food Safety and Consumer Protection Law 13/2006, art 4
([16]) Law of 11 May 2003 on research on in vitro embryos.

production of embryos in vitro for research purposes unless the purpose of the research cannot be achieved by research on surplus embryos. Egg fertilisation is allowed if the egg donor is of a legal age and has given written consent and the fertilisation is justified.

GMOs

Royal Decree regulating the deliberate release into the environment and the placing on the market of genetically modified organisms or products containing (2004)([17]) is the standard GMO instruments which regulates the contained use, deliberate release and marketing of GMOs and GMO products. It provides for the safety and reporting requirements as well as the procedure for obtaining the relevant licences and penalties for breaches of the Decree.

Animal law

The Law on Animal Welfare provides that any invasive or non-invasive use of animal for experimental or other scientific purposes which may cause the animal pain, distress or permanent damage is not allowed unless there is some large benefit ([18]). This includes any intervention that is designed or likely to result in the birth or incubation of an animal in such a condition or creation and maintenance of a genetically modified animal line in such condition, but does not include the killing of animals solely for use their organs or tissues.

Patents

The Patent Law of March 28, 1984 (as amended on December 22, 2008) appears to be a standard European patent legislation ([19]). Article 4 prohibits patents for methods for cloning human beings, techniques for 'splitting' embryos aimed at creating a human beings; methods for modifying the genetic identity of humans; methods for modifying the genetic identity of animals when there is not an overwhelming medical benefit to humans or animals; the human body at different stages of its developments and elements isolated from the body.

3.3 Bulgaria

General Outline

Bulgaria's legislative coverage of topics relating to genetics is fairly comprehensive with the exception of genetics in the criminal context. Despite considerable effort, no primary legislation on this topic could be located. It is possible that the relevant provisions are contained in Regulations, and hence outside of the scope of this review. The most notable outlier is Article 8(9) in the Child Protection Act (2000) which instructs parents and guardians of children not to allow their children to participate in advertisements or other form of communications for genetically modified foods. No specific legislation relating to gene technologies was found in this jurisdiction.

Most relevant legislation: Relevant legislation in this jurisdiction includes the Patents Act, Health Law and the Law on Genetically Modified Organisms.

([17]) Royal Decree regulating the deliberate release into the environment and the placing on the market of genetically modified organisms or products containing GMOs (2004).
([18]) Law on Animal Welfare.
([19]) The Patent Law of March 28, 1984 (as amended on December 22, 2008)

Patents

The patent law (1993) limits what may be subject to patent ([20]). Similarly to Austria, Bulgaria prohibits patentability for inventions where their commercial use would violate public order and morality, which explicitly includes methods for cloning humans, methods for modifying the genetic identity of human embryos and the use of human embryos for commercial purposes, as well as methods for genetically modifying animals where the effected pain is large and without any substantial benefit to humans or animals. The human body and its elements, including the sequence or a partial sequence of a gene, are not patentable but can be when an element isolated from the human body is obtained by a technical process even if the elements are identical to that of a natural element. This appears to permit patentability of gene sequences in some circumstances.

Health

The Health Law (2005) touches on genetics in healthcare and medical research ([21]). This law prohibits the use of IVF to select the sex of the baby, unless it is done to prevent a sex-linked genetic disease, and it is prohibited to use assisted reproduction techniques which aim to transmit genetic information of only one individual to the offspring. The law further provides for genetic treatments to prevent hereditary diseases occurring in children. The legislation also covers some basics relating to genetic studies and the required licences for any such research, as well as a provision to the effect that genetic laboratories may establish DNA banks for the collection and storage of genetic material for scientific and medical purposes. Importantly, Article 198 of the Law provides that medical scientific research on humans shall not be carried out with genetic engineering products which may lead to transmission of these changes to the offspring of the subjects. It appears therefore that permanent and inheritable changes in a person's genetic makeup are prohibited.

Animal law and environment and GMOs

Bulgaria has numerous laws regulating the access and management of genetic information of animals, including fish. The Animal Law (2000) provides for the management of genetic resources of animals and establishes a national genetic bank which contains animal genetic information ([22]). The Act appears mainly aimed at agriculture and food production. The purpose of the genetic bank is to ensure biodiversity of livestock into the future. The Law on Fish and Aquaculture (2001) provides for safety measures and handling of genetic materials (eggs etc.) of fish, particularly its sale ([23]). Law on Biological Diversity (2002) specifies as one of its aims the preservation and conservation of the genetic diversity of plants and animals ([24]). Overall, in Bulgaria there appears to be a strong focus on the fauna and flora diversity and its protection and exhibits wariness in introducing GMOs into the environment as specified in the Environmental Protection Law (2002), whereby GMO release is expressed as a potential danger to the environment, animals and humans ([25]).

([20]) Patent Law (1993)
([21]) Health Law (2005) arts 127, 135, 138, 139, 144, 198
([22]) Animal Law (2000)
([23]) Law on Fish and Aquaculture (2001)
([24]) Law on Biological Diversity (2002)
([25]) Environmental Protection Law (2002)

The Law on Genetically Modified Organisms (2005) is near identical to its equivalents across the EU and regulates the closed use of GMOs, deliberate release of GMOs as well as marketing of GMOs ([26]).

Food safety and consumer affairs

The Child Protection Act (2000) instructs parents to not allow their children to participate in advertisements or other forms of communication for genetically modified foods ([27]). This provision appears to be the only one of its kind located in the course of this review.

3.4 Croatia

General Outline

No specific gene technology legislation could be identified for Croatia, and the legislation which relates to aspects of genetics is mainly focused on consumer affairs, criminal procedure, IVF, GMOs and patents.

Most relevant legislation: The most relevant legislation is the Law on the Protection of Patients' Rights (2004) which prohibits the alteration of human germ line.

Patents

The provisions of the Croatian Patent Law (2003) are broadly the same as in most EU jurisdictions ([28]). The Patent Law prohibits patents for the human body but allows for patentability of a gene or a segment of a gene in some circumstances. It prohibits patents for methods for cloning humans, modifying genetic identity of the human germ line, use of human embryos for commercial purposes and methods for genetically modifying animals where there is no substantial health benefit for animals or humans.

Health laws

The Law on the Protection of Patient's Rights (2004) specifies that interventions directed at changing the human genome can only be undertaken for preventative or therapeutic purposes and no interventions are allowed with the view to changing the patient's germ line ([29]).

The Act on Assisted Reproduction (2012) regulates IVF, genetic counselling during pregnancy and prohibits certain acts such as creating genetically identical human beings ([30]). It provides for rules on donating eggs and sperm as well as embryos and the allowed use of these; and also establishes a central registry with information on persons who used IVF and for their children. The Act also prohibits using any data collected during any IVF procedure for any other purpose apart from aggregate statistical indications. It is also prohibited to select the sex of a child unless it is to prevent a sex-linked condition and research on embryos and their alteration is generally prohibited.

([26]) Law on Genetically Modified Organisms (2005)
([27]) Child Protection Act (2000)
([28]) Patent Law (2003)
([29]) Law on the Protection of Patients' Rights (2004) art 22
([30]) Act on Assisted Reproduction (2012) arts 4, 9, 19, 27, 37, 50, 53

The Law on Medicines (2013) regulates the use of GMOs in medicines and gene therapy; and specifies what ethical approvals are needed in those circumstances ([31]). In all cases the Central Ethics Committee must give its permission and opinion on the admissibility of clinical trials for gene therapy and for medicines containing GMOs.

Criminal context

The Criminal Procedure Code provides for how DNA is to be handled during and after criminal investigations and which persons have the authority to access the genetic data, when the data are to be destroyed and what consents are necessary from the subject of the investigation ([32]).

GMOs, environment and food safety

The Act on Genetically Modified Organisms (2005) is standard and very similar to other European legislation on GMOs ([33]). It specifies what licences are necessary for contained use of GMOs, deliberate release of GMOs as well as their placement on the market. The Food Act (2013) specifies that all food can be deemed unsafe on the basis of containing GMOs and the Croatian Food Agency is to provide reports on food safety reports on GMO-containing food ([34]).

The Law on Nature Protection (2013) specifies biodiversity as one of its goals and prohibits the introduction of GMOs into the environment without a relevant permit ([35]). The law further regulates access and use of the wildlife animal's genetic material.

3.5 Cyprus

General Outline

No specific legislation on gene technologies could be found, but Cyprus has extensive coverage of legislation relating to GMOs, IVF, environmental protection, personal data protection and food safety. Only limited legislation relating to the use of DNA in criminal contexts could be located, which indicates any other such provisions are likely contained in local regulations as opposed to primary legislation. The legislation described below as 'health laws' is the most directly connected to genetic technologies and permitted activities in relation to genetics.

Most relevant legislation: The most relevant instruments are the Bioethics (Establishment and Functioning of the National Committee) Law of 2001 (150(I)/2001) and the Medically Assisted Reproduction Law of 2015 (69(I)/2015).

Patents

The Patent Law of 1998 is broadly of the same character as the patent laws all across the EU ([36]). It excludes patentability of the human body and its elements, except for in

([31]) Law on Medicines (2013), arts 14, 15
([32]) Criminal Procedure Code (2008)
([33]) The Act on Genetically Modified Organisms (2005)
([34]) The Food Act (2013)
([35]) Law on Nature Protection (2013) arts 7, 55, 88, 89

certain circumstances the elements, including a sequence of a gene may be patented. The Act further prohibits patenting of methods for human cloning, modifying the germ line identity of humans, using embryos for industrial or commercial purposes and genetically modifying animals in situations where there is no substantial medical utility for humans or animals.

Health laws

Cypriot law regulates IVF through the Medically Assisted Reproduction Law of 2015 (69(I)/2015) which outlines the procedures for IVF as authorised by law and when pre-implantation genetic diagnosis can be carried out ([37]). The Law prohibits sex-selection of embryos except for the cases where there is a high probability of the child developing a sex-linked genetic disease. The Law also provides for when genetic counselling is to be made available to prospective parents/donors and how the genetic facilities are to be run and inspected.

The Bioethics (Establishment and Functioning of the National Committee) Law of 2001 (150(I)/2001) establishes the National Bioethics Committee ([38]). The Committee analyses and evaluates projects relating to genetics and is also responsible for informing the public on its findings and monitoring implementation of the international obligations of Cyprus relating to genetics.

Data protection

The Personal Data Processing Act (Protection of Individuals) Law of 2001 (138(I)/2001) covers data protection of sensitive personal data, which does not specifically include genetic information but does include health information and information relating to ethnicity and race, which could presumably include some genetic information ([39]). The Act provides for stronger protections for sensitive data and limits the permitted uses of such data.

GMOs

Cyprus has a multitude of legislative instruments covering GMOs. The Biological Production Law of 2001 (160(I)/2001) specifies that GMO foods must be labelled as such and gives the relevant Minister the power to issue regulations for GMO foods ([40]). Both the Genetically Modified Organisms (Release into the Environment) Law of 2003 (160(I)/2003) and the Genetically Modified Organisms (Limited and Contained Use) Law of 2004 (15(I)/2004) provide for what permits are necessary when using GMOs, the procedure for acquiring permits as well as safety obligations placed on those using GMOs. These two laws are broadly identical to those in other EU jurisdictions. The Food (Control and Sale) Law of 1996 (54(I)/1996) specifies that GMO-containing foods must be labelled as such and must be placed on separate shelves in stores, apart from other food ([41]).

3.6 Czech Republic

General Outline

([36]) Patent Law of 1988 (16 (I)/1998)
([37]) Medically Assisted Reproduction Law of 2015 (69(I)/2015)
([38]) The Bioethics (Establishment and Functioning of the National Committee) Law of 2001 (150(I)/2001)
([39]) Personal Data Processing Act (Protection of Individuals) Law of 2001 (138(I)/2001, arts 6, 8
([40]) Genetically Modified Organisms (Release into the Environment) Law of 2003 (160(I)/2003)), arts 3,4,5,22
([41]) The Food (Control and Sale) Law of 1996 (54 (I)/1996)

There seems to be no specific legislation targeted at genetic technologies, the most closely related law seems to be the Penal Code which prohibits certain acts with genetic data and health laws regulating IVF and genetic testing in people. Other areas addressed by relevant Czech laws are protection of the environment, agriculture, use of GMOs and data protection. Overall, fewer legislative instruments with direct relevance were located in this jurisdiction.

Most relevant legislation: N. 227/2006, N. 40/2009, N. 227/2006, N. 202/2017, N. 66/2013

Health laws

Law N. 202/2017 relates to specific medical services ([42]). It regulates genetic testing in patients and specifies the circumstances in which genetic testing is permitted and what procedure must be followed. Law N. 66/2013 which regulates the provision of medical services, specifies when genetic information of a person can be used and in what way ([43]).

Patents

Law N. 206/2000 on the protection of biotechnological inventions prohibits in much the same way as other European jurisdictions patents to be issued for procedures, which alter the genetic identity of animals in a way which does not cause a substantial benefit to human or animal health and prohibit the patentability of gene sequences in humans ([44]).

Criminal context

Law N. 227/2006 is the Penal Code which specifies certain acts as offences; these include handling and using human genetic information in prohibited ways ([45]). These prohibited acts relate especially to breaches of confidentiality.

Environmental laws, agriculture and GMOs

The Czech Republic has numerous laws relating to protecting the environment and GMOs. Law N. 148/2003 regulates the conservation and usage of genetic resources of plants and microorganisms important for agriculture and the food supply. The law establishes the National Program for storing genetic material of plants and microorganisms and specifies how the material is to be collected, evaluated, conserved and used. Law N. 300/2009 regulates the introduction of seeds into the environment for agricultural purposes and specifies where such seeds may be genetically modified ([46]). Law N. 232 is concerned with protection of the genome of forests and establishes a National Program for this purpose. Law N. 60/2017 establishes a genetic registry for livestock which is aimed at preserving genetic diversity in the agricultural animals ([47]).

Law N. 78/2004 regulates the use, licensing and safety of GMOs ([48]). The legislation is much the same as its equivalents in other European jurisdictions and outlines the

([42]) Law N. 202/2017
([43]) Law N. 66/2013
([44]) Law N. 206/2000
([45]) Law N. 227/2006
([46]) Law N. 300/2009
([47]) Law N. 60/2017
([48]) Law N. 78/2004

handling procedures for GMO products, their risk evaluation and information protection; it has a specific section on introduction of GMOs and GMO products into the environment and the market, as well as provisions on the import, export and transit of GMOs and GMO products. Law N. 371/2016 focuses on the introduction of GMOs or GMO products on the market ([49]).

Data protection

Law N. 101/2000 is the Czech Privacy Law and in Article 4 it explicitly includes genetic data as sensitive personal information, thus subjecting genetic data to greater measures of protection ([50]). The Law further specifies the obligations on those storing or processing sensitive personal information.

3.7 Denmark

General Outline

Denmark has a fairly comprehensive coverage of the most common areas of legislation relating to genetics. There appears to be no specific legislation addressing gene technologies, but many closely related instruments have been found, for example the Act on Cloning and Modification of Animals and the Environment and Genetic Engineering Act (despite its name this legislation largely covers GMO licensing). The areas covered by the relevant Danish legislation range from the DNA database for criminals to immigration provisions. No directly relevant legislation relating to genetics and health could be located, which indicates its existence in the form of regulations rather than primary legislation.

Most relevant legislation: Act on Cloning and Modification of Animals, Environment and Genetic Engineering Act, Patent Act

Patents

The Patent Act No. 221 of 26/2/2017 is very similar to the other patent legislation available in other European jurisdictions ([51]). It provides that inventions may be patentable even if they concern a product consisting of a biological material which may be genetic information. The Act prohibits patents for methods for cloning humans, methods for modifying the genetic identity of human sex cells. It also prohibits the use of embryos for industrial or commercial purposes and methods for modifying animal genetic identity which may cause disease except in cases of significant medical utility for humans or animals.

Criminal context

The Law on processing of personal data by law enforcement authorities No. 410 of 27/4/2017 regulates how police and associated authorities can process personal data ([52]). The legislation includes genetic data as sensitive data which is protected more stringently than other personal data; and cannot be used for the unambiguous identification of a natural person. Similarly, the Act on Establishment of a central DNA

([49]) Law N. 371/2016
([50]) Law N. 101/2000
([51]) Patent Act No 221 of 26/2/2017 s1
([52]) Law on the processing of personal data by law enforcement authorities No 410 of 27/4/2017

profile register No. 434 of 31/5/2000 establishes a central DNA profile register ([53]). The Act specifies the rules under which the register is to operate and who can access the genetic information; and limits the scope of information which can be included to that which is of police significance in connection with personal identification. The Act further provides for when data are to be deleted and when consent must be sought from the subjects.

Environmental laws and GMOs

Law on Benefit Sharing with the Use of Genetic Resources No. 1375 of 23/12/2012 implements the Nagoya Protocol into Danish law and specifies when Denmark will share genetic resources ([54]). The Act also prohibits the use of traditional knowledge related to genetic resources held by indigenous communities if that knowledge has been acquired in violation of the law.

The Environment and Genetic Engineering Act No.9 of 4/1/2017 regulates the space of GMOs ([55]), it clarifies when licences are necessary for the use of GMOs and provides for use of GMOs in closed systems, deliberate release of GMOs and marketing of GMOs, as well as the transport, import and transit of GMOs and specifies the risk assessments necessary as well as the safety precautions which must be taken. The Act on Cultivation of Genetically Modified Crops No. 28 of 4/1/2017 limits when GMO crops may be used and delegates power to the relevant Minister to issue regulations in connection with GMO crops ([56]).

Animal laws

The Act on Cloning and Modification of Animals No 478 of 15/5/2014 provides that cloning of animals is permitted with authorisation from the Animal Research Inspectorate ([57]). Cloning will only be allowed for the purposes of basic research, applied research aimed at improving the health and environment, production of breeding animals and producing substances of major benefit to health and the environment or education and training at universities and higher education institutions. Penalties are imposed for breaches of this Act.

Immigration laws

The Aliens Act no 1117 of 2/10/2017 provides for instances where during immigration proceedings genetic information can be used to identify persons and those persons' relatives ([58]). DNA tests are permitted when an alien claims to be related to a Danish resident and to otherwise determine the identity of the person.

3.8 Estonia

General Outline

Estonia has a comprehensive network of laws which relate to genetics. The most crucial instrument is the Human Gene Research Law which specifically addressed genetic

([53]) The Act on Establishment of a central DNA profile register No 434 of 31/5/2000
([54]) Law on Benefit Sharing with the Use of Genetic Resources No 1375 of 23/12/2012
([55]) Environment and Genetic Engineering Act No 9 of 4/1/2017
([56]) Act on Cultivation of Genetically Modified Crops No 28 of 4/1/2017
([57]) Act on Cloning and Modification of Animals No 478 of 15/5/2014
([58]) Aliens Act no 1117 of 2/10/2017

research and handling of genetic material and data. This law is one of the most comprehensive instruments found in the review addressing genetic research. Other areas covered by Estonian law are patents, data protection, DNA database in criminal proceedings as well as GMOs and environmental protection.

Most relevant legislation: Human Gene Research Law (2000), Artificial Insemination and Embryo Protection Act (1997), Patent Act (1994)

Genetic research

The Human Gene Research Law (2000) regulates genetic research and DNA samples, handling and procedure ([59]). It establishes a gene database and specifies the rights of donors and clarifies who has access to genetic information. Section 6 of the law provides that gene research and testing is allowed for the purpose of exploring and describing the relationship between genes, the environment and people's lifestyles and exploring how to prevent or treat illnesses. DNA samples must be provided voluntarily. The law has extensive provisions specifying the rights of donors to know their genetic information, to order the destruction of their genetic information as well as obligations on persons processing the information to handle it with respect and according to the donor's wishes. The law further specifies how the DNA is to be coded and de-identified for research purposes and prohibits any discrimination in employment relationships as a result, or on the basis of, a person's genetic information. The law also prohibits any discrimination based on genetics in the insurance context, whereby insurance companies are prohibited from imposing different insurance conditions on people with different inheritance risks. The law also provides for the establishment of an ethics committee which scrutinises research.

Health laws

The Artificial Insemination and Embryo Protection Act (1997) prohibits the sex selection of embryos in IVF procedures except where there is a high probability of occurrence of a genetic disease linked to the sex chromosome ([60]). It is also prohibited to clone embryos or fuse the genetic information of embryos in order to create a cell fusion, if one of the embryos is a human embryo. The Medicinal Products Act (2004), specifies what permits clinical trials must obtain before commencement and the special conditions in circumstances where the proposed trial includes genetically modified organisms ([61]). The Procurement, Handling and Transplantation of Cells, Tissues and Organs Act (2015) regulates the handling of tissues and cells especially in the context of transplants ([62]).

The Occupational Health and Safety Act (1999) provides that no employees shall be endangered by biological hazards in the workplace; biological hazards include genetically modified organisms ([63]).

Patents

The Patents Act (1994) is much the same as all the other patent legislation across the EU ([64]). It prohibits patents for processes for cloning humans, processes for modifying the germ line genetic identity of humans, uses of human embryos for commercial purposes,

([59]) Human Gene Research Law (2000)
([60]) Artificial Insemination and Embryo Act (1997)
([61]) Medicinal Products Act (2004)
([62]) Procurement, Handling and Transplantation of Cells, Tissues and Organs Act (2015)
([63]) Occupational Health and Safety Act (1999)
([64]) Patents Act (1994)

processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to health of humans or animals.

Data protection

The Personal Data Protection Act (2007) covers the area of protection and handling of personal data, including genetic data ([65]). Genetic data are expressly included as sensitive personal data and are thus subject to greater protections provided by most of the sections 12 to 42 of the Act. There are strict limits on how sensitive personal data may be processed and there is an obligation to register all processing of sensitive personal data with the relevant Authority.

Criminal context

The Forensic Examination Act (2001) establishes a National DNA Database for storing and collecting DNA of prisoners and suspects in criminal matters ([66]). The law specifies who and when can access the DNA information and when the information is to be destroyed. The Imprisonment Act (2000) provides for the way prisoners' DNA samples are to be handled ([67]). Each person admitted to prison shall have a DNA sample collected for the purposes of identification, detection and prevention of offences. This DNA will be stored in the State DNA Register.

GMOs

The Contained Use of Genetically Modified Micro-organisms Act (2001) and the Release into Environment of Genetically Modified Organisms Act (2004) are the standard GMO laws which regulate licensing of the use of GMOs and provide for use of GMOs in contained spaces, deliberate release of GMOs and marketing of GMOs ([68]). The laws provide for GMO export, import and transit as well as the required safety measures, reporting obligations and what information regarding the use of GMOs by individuals (be they companies or natural persons) must be publicly available.

Environmental laws

The Nature Conservation Act implements the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, Regulation (EU) No 511/2014 of the European Parliament and Council on compliance measures for users of the Nagoya Protocol in the Union, which must be followed ([69]).

3.9 Finland

General Outline

Finland has numerous laws relating to genetics on many topics varying from biobanks, food safety, penal provisions, paternity testing, GMOs and medical research. Notable law is the Biobank Law, which establishes a biobank for storage of human tissue samples as

([65]) Personal Data Protection Act (2007)
([66]) Forensic Examination Act (2001)
([67]) Imprisonment Act (2000)
([68]) Contained Use of Genetically Modified Micro-organisms Act (2001); Release into Environment of Genetically Modified Organisms Act (2004)
([69]) Nature Conservation Act (2004)

well as the Medical Research Act which specifies that an ethics committee must give approvals for research projects. Another outlier is the prohibition for employers to require or know results of genetic tests of their employees as per the Act on the Protection of Privacy in Working Life.

Most relevant legislation: Medical Research Act, Biobank Law, Gene Technology Act and Patents Act.

Health and social laws

The Medical Research Act specifies that an ethics committee must approve research proposals and outlines which factors the committee is to consider in deciding on an application ([70]). The Act further specifies that the ethics committee has a longer time period for its decision when the application relates to gene therapies and /or genetically modified organisms. The Biobank Law establishes a biobank for storage of human tissue samples. The Biobank law does not directly address the genome or DNA but is sufficiently closely related to warrant a short mention. It regulates how samples collected from humans are to be stored and handled. It is also meant to protect the privacy and control of patients/subjects over the collected samples ([71]).

The Act on the Protection of Privacy in Working Life prohibits employers to require employees to undergo genetic testing or request results of any genetic tests the employees have had previously. The Law on Genetic Research regulates paternity investigations and provides for when such test can be authorised. The Paternity Act further specifies when DNA testing can be performed to identify the father of a person and where such tests can be performed without the consent of the potential test subject (potential or suspected father).

Patents

The Patents Act is much the same as essentially all the European patent legislation ([72]). It prohibits patents for cloning of humans, processes for modifying the germ line of humans, commercial uses of human embryos and processes for modifying the genetic identity of animals which is likely to cause them suffering without any substantial medical benefit to humans or animals.

GMOs

The Gene Technology Act aims to promote safe use and development of genetic engineering and to protect human and animal health ([73]). The Act establishes the Genetic Engineering Board which oversees the obligations of persons using GMOs. The Act provides for licensing for the use of GMOs in closed space, their deliberate release as well as marketing of GMOs or GMO products. It outlines reporting obligations, safety measures and risk assessments which have to be in place in order to obtain a GMO use licence.

Criminal context

([70]) Medical Research Act 9.4.1999/448, s10d
([71]) Biobank Law 30.11.2012/688
([72]) Patents Act 15.12.1967/550, ss1, 1b, 3a
([73]) Gene Technology Act 17.3.1995/377

The Penal Code specifies offences related to genetics ([74]). It is an offence to clone a human, altering and generating human germ cells and animal genetic material and the generation of a human by combining embryos. These offences are punishable by imprisonment of up to 2 years. It is also prohibited to intentionally spread GMOs in violation of the Gene Technology Act and export GMOs without a licence.

The Coercive Measures Act provides for situations when DNA can be collected from criminal suspects and specifies how the samples and any resulting data are to be handled, stored and destroyed ([75]).

Immigration

The Aliens Act provides that DNA analysis may be used to prove a family relationship between persons in the context of immigration proceedings ([76]). The Act further provides how such analysis is carried out, what happens with the data afterwards and what safety measures must be in place for a sample collection.

Environmental laws, agriculture and food safety

The Seed Trade Law limits the use of GMO seeds in Finnish agriculture and provides that there has to be a register of the verities of seeds, with a special section for GMO seeds ([77]). Similarly the Law on Trade in Forest Reproductive Material prohibits and limits the GMO material which is to be used in forests ([78]).

The Food Act implements the Regulation EC No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. It also implements the Regulation (EC) No 1830/2003 of the European Parliament and of the Council on the traceability and labelling of genetically modified organisms and traceability of foods and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ([79]).

3.10 France

General Outline

Most of the relevant provisions are contained in the Public Health Code which provides for when medical genetic research can be carried out and what provisions, namely ethical considerations, must be considered and abided by. Other than that the French Codes cover environmental, penal as well as agricultural aspects as related to genetics.

Most relevant legislation: Public Health Code, Penal Code and Bioethics Law

Health laws

([74]) Penal Code 19.12.1889/39, ch22 art 4, ch34 art 4, ch44 art 9, ch48 art 1
([75]) Coercive Measures Act 22.7.2011/806
([76]) Aliens Act 30.4.2004/301
([77]) Seed Trade Law 4.8.2000/728
([78]) Law on Trade in Forest Reproductive Material 5.4.2002/241
([79]) The Food Act 13.1.2006/23

The Public Health Code is the most significant legislative instrument with respect to genetics identified in the review ([80]). It contains provisions on genetic counselling, when such counselling is to be provided and what qualifications genetic counsellors must have. It further defines what genetic characteristics mean and what is genetic identification. The Code also regulates gene therapy preparations and xenogeneic cell therapy preparations and importantly, Articles R1125-7 to R1125-13-1 regulate genetic research. The Code also provides for when prenatal and pre-implantation diagnosis can be carried out and who is qualified to perform the procedures; and it also regulates the examination of genetic characteristics by DNA fingerprinting for medical purposes.

The related Law on Bioethics which is also contained in the Public Health Code specifies when abortions are permitted and when research on genetics can be performed ([81]). As per Article L2151-2 in vitro design or cloning of human embryos for research purposes is prohibited, as is the creation of transgenic or chimeric embryos. Generally speaking as per Article L2151-5 research on human embryos, embryonic stem cells and stem cell lines is prohibited. However, such research can be permitted if the scientific relevance of the research project is established, when the research is likely to allow major medical progress and the research cannot be performed any other way without the use of human embryos, embryonic stem cells or stem cell lines. Any such projects must be authorised by the Biomedicine Agency and adhere to the ethical codes promulgated by the Agency. The Article also specifies which embryos may be used for such research.

Criminal context

The Penal Code outlines numerous offences related to genetics when a person breaches provisions relating to examination of a person's genetic characteristics and breaches provisions of biomedical ethics ([82]). The Code also provides and establishes the national automated DNA file and provides how it shall be operated and who has access to the information thereby contained.

Environmental laws

The Environmental Code contains the standard GMO legislative provisions on the contained use of GMOs ([83]), the deliberate release of GMOs and the marketing of GMOs; further detail can be found in the Law on Genetically Modified Organisms which regulates the licencing of the use of GMOs ([84]). The Code also specifies when GMO plants can be used, when seeds and seedlings containing GMOs can be planted and provides for protection of the environment and biodiversity of the local fauna. The law on future of agriculture, food and the forest specifies what role GMOs have to play in the future; and the Law prohibiting the cultivation of genetically modified corn varieties prohibits the cultivation of GMO corn and maize.

3.11 Germany

General Outline

Germany has a significant number of laws which touch on genetics, with the Embryo Protection Act being the most relevant for present purposes.

([80]) The Public Health Code
([81]) Law on Bioethics
([82]) Penal Code
([83]) Environmental Code
([84]) Law on Genetically Modified Organisms

Most relevant legislation: Embryo Protection Act (1990), Patents Act (1980) and the Genetic Testing Act (2009)

Patents

The Patent Law (1980) is a standard patent legislation comparable to the other European acts on patents ([85]). The Law prohibits patents for methods for cloning humans, modifying the germ line of humans and using human embryos for commercial purposes as well as for methods for genetic modification of animals in a way capable of causing suffering without a substantial medical benefit to humans or animals.

Embryo research and health law

The Embryo Protection Act (1990) is the most significant legislative instrument located in the German jurisdiction review ([86]). It prohibits selection of embryos on the basis of sex except for cases where it is to prevent Duchenne muscular dystrophy or a similarly serious sex-linked genetic disease. The qualifying diseases must be so considered by the appropriate national body. The Act regulates the provision of pre-implantation genetic diagnosis, and in Article 3a it prohibits the genetic examination of the cells of an embryo in vitro prior to intrauterine transfer; breach of these provisions is an offence. Preimplantation diagnosis is allowed if the parents have a high risk of a serious hereditary disease and the patient must be informed of all the possible consequences of the procedure and an ethics committee must approve the procedure. The Act in Article 5 strictly prohibits the alteration of the human germ line and provides that any breaches of the provision are punishable by up to 5 years in prison. There are some exceptions to the prohibition if the cell is not used for fertilisation and not transferred to an embryo, foetus or a human. The Act in Article 6 further provides that it is prohibited to clone an embryo and place any such embryo into the womb. In Article 7 the Act prohibits creation of chimera and hybrid formation and placing any such creations into a womb.

The Infection Protection Act (2000) regulates epidemiological surveillance and includes a special provision to provide for cases where human genetic information is involved ([87]), in which case measures must be taken to avoid the identification of the data subject. The Medicines Act (2005) specifies the procedure for getting an Ethics Committee approval for medicines and provides for a special regime and extends time for the Committee to decide when the drugs or therapies are gene therapies or contain genetically modified organisms ([88]).

The Genetic Testing Act (2009) regulates genetic testing in humans ([89]). The Act provides when and how genetic testing can be performed and how any collected genetic information and samples are to be handled. It also prohibits discrimination based on genetic characteristics in all contexts of life as well as prohibits discrimination based on the refusal to take a genetic test. The Act provides circumstances in which genetic counselling should be provided to subjects and how results of tests are to be communicated, as well as how quality of the test is to be assured. Furthermore, the Act provides that it is prohibited to require genetic data from a person in the health insurance context, but it is allowed in the contact of occupational disability and nursing

([85]) Patent Law (1980) No 1/1981
([86]) The Embryo Protection Act (1990) No 69/1990
([87]) Infection Protection Act (2000) No 33/2000
([88]) Medicines Act (2005)
([89]) Genetic Testing Act (2009) No 50/2009

care insurance. The Family Law Procedural Law (2009) specifies when samples of DNA can be taken and compared in the context of determining familial relationships.

Criminal context

The Code of Criminal Procedure (1987) provides for how DNA is to be used in the context of criminal investigations ([90]), it limits the scope of genetic analysis which can be performed on samples and specifies how DNA samples can be collected and when consent for collection is not necessary.

GMOs

The Genetic Engineering Act (1993) implements the EU Council Directive 90/219 EEC of 23 April 1990 on the contained use of GMOs ([91]), it specifies how licensing and use of GMOs for contained use works and when GMOs can be placed on the market, as well as outlining the safety requirements necessary to obtain a licence. The EC Genetic Engineering Implementing Act (2004) provides for monitoring, labelling and processing of GMO foods and specifies when food items can be labelled as 'produced without the use of genetically modified food' ([92]).

Environmental laws, animal law and agriculture

Germany has an abundance of laws relating to the environment and agriculture which touch on genetics. The Seed Traffic Law (2004) regulates the marketing and handling of plant materials and provides for special treatment of GMO seeds and seedlings ([93]). The Animal Breeding Law (2006) aims to obtain and maintain diversity of animals and provides for measures to monitor the genetic diversity of livestock populations and the internal diversity of animal breeds ([94]). The Federal Nature Conservation Act (2009) provides for what permits are necessary to release wildlife into the environment but specific regime is in place for animals being released to the area of their genetic origin ([95]).

3.12 Greece

General Outline

The Greek laws on the genome have proven extremely difficult to locate due to the author's inability to speak Greek and the lack of any in-text search function on the Greek law site. The laws which could be located cover topics of environment protection and biodiversity and IVF.

Most relevant legislation: Law 3305/2002 on Medical Support in Human Reproduction and Law 3305/2005 Applying Medically Assisted Reproduction – both laws were amended by Law 4272/2014 on Human Transplants, Mental Health and Medical Assisted Reproduction.

([90]) Code of Criminal Procedure (1987)
([91]) Genetic Engineering Act (1993) No 67/1993
([92]) EC Genetic Engineering Implementing Act (2004) No 29/2004
([93]) Seed Traffic Law (2004) No 37/2004
([94]) Animal Breeding Law (2006)
([95]) Federal Nature Conservation Act 2009 No 51/2009

Health Laws

The Law 3089 on Medical Support in Human Reproduction introduced a new chapter to the Greek Civil Code, covering when permits can be obtained for women to undergo IVF and whose sperm can be used etc.([96]). The legislation also provides that when there is a high risk of an inherited disease, embryos may be selected in order to avoid the inherited disease from occurring (Article 1455). The legislation does not directly address genetics or embryo research.

The Law 3305 Applying Medical Assisted Reproduction imposes strict conditions for Medically Assisted Reproduction, stipulating that it is only to be employed when it is necessary from a medical perspective (i.e. inability to procreate without MAR or the high risk of an inherited disease) and the interested female individual is under 50 years old. It contains an extensive definitions section of terms such as cryopreservation of gametes, zygotes etc. ([97]). The legislation operates to set up biobanks for the storage of genetic information and embryos as well as outline the principles of bioethics to be employed when performing IVF. The legislation also covers when pre-implantation genetic diagnosis can be performed. Further it also governs research on cells and embryos which are not destined for pregnancy. Research can be carried out to expand human knowledge and to improve diagnosis and treatment methods for infertility as well as contraception, to develop and control treatment techniques for genetic diseases and abnormalities and to study the biology of embryonic cells and their possible therapeutic uses. A licence is necessary for any such research. The law also creates criminal offences for the cases where acts are committed that increase the risks connected with Medically Assisted Reproduction (e.g. deficient medical procedures, disregarding the prescribed by law age limits etc.).

Law 4272, to the extent that it amends the previous two legislative instruments, was enacted in the interest of clarifying 'vague or problematic' provisions in them and ensure that they respond to the challenges of applying Medically Assisted Reproduction in practice. The main rationale was to enhance the protection afforded to the (female) individual seeking to give birth by MAR and the child that will be born, while also considering the grave difficulties faced by medical scientists involved in this activity. The main amendments include the possibility of extending the duration of cryopreservation of genetic materials in case no communication with the interested parties is possible (article 14), the legal power to donate gametes without the consent of one's partner / spouse (article 15), a set of administrative changes meant to streamline the operation of MAR Units and Biobanks (articles 18, 19) and a reduction to the criminal sentence imposed to those who participate in selling or purchasing genetic materials (article 20).

One should also note the role of the National Authority on Medically Assisted Reproduction within the Greek regulatory environment. Their published framework-decisions, mainly 170/2008, 670/2008, 1287/2008 and 2683/2014, have been instrumental in providing authoritative guidance on the above legislative instruments for medical practitioners.

Environmental protection and biodiversity

The Law 3208 on the Protection of Forest Ecosystems provides in Article 19 that biodiversity of forests is one of the aims of the legislation ([98]). The Law 3937 of 15 March

([96]) Law 3089 on Medical Support in Human Reproduction
([97]) Law 3305 Applying Medical Assisted Reproduction.
([98]) Law 3208 on the Protection of Forest Ecosystems.

2011 on Biodiversity and other Aspects of Conservation provides for the measures to achieve biodiversity in nature ([99]).

3.13 Hungary

General Outline

The laws relating to genetics are fairly extensive in Hungary. The most directly relevant legislation is the XXI Law on the Protection of Human Genetic Data, on the Rules of Human Genetic Testing and Research and Operation of Biobanks (2008). The areas covered by relevant legislation cover criminal, data protection, environmental protection as well as health laws, agriculture and patents.

Most relevant legislation: XXI Law on the Protection of Human Genetic Data, on the Rules of Human Genetic Testing and Research and Operation of Biobanks (2008)

Patents

XXXIII Law on Patents and Protection of Inventions (1995) limits the patentability of parts of the human body and specifies that medical or surgical procedures for treatments of humans or animals as well as diagnostic procedures for the human body shall not be considered industrially applicable ([100]). This Act appears to be missing the prohibition on patentability present in many other patent legislations around Europe. There seems to be no prohibition on cloning, human embryo commercial applications or the like. It must be noted that this could be as a result of inadequate translation of the original text and hence not because of a real omission in the legislation.

Genetic research and health laws

XXI Law on the Protection of Human Genetic Data, on the Rules of Human Genetic Testing and Research and Operation of Biobanks (2008) aims to protect people's genetic information ([101]). It provides how genetic data is to be handled, when can it be used for research and how genetic analysis can be carried out and provides rules for biobanks. Genetic testing can be performed for prevention, diagnostic, therapeutic or rehabilitation purposes and solely on the basis of medical interest. People who are in possession of genetic data have a responsibility to protect the data. The law specifies how people are to be notified of genetic test results and what consent must be given before any testing is done. Genetic data are to be used mainly only for the purposes for which they were collected, but in limited circumstances this can be extended. Genetic studies can use de-identified genetic data to determine the distribution of genetic variants between individuals.

The LXXIX Law on the Protection of Foetal Life (1992) regulates the provision of abortions and aims to protect foetal life ([102]). It provides for the services of genetic counsellors and how these services feed into the assessment of permitted abortions. Pregnancies may be aborted until the 20th week or later if there is too great a genetic risk to the health of the foetus. The CLIV Law on Health (1997) also provides for other

([99]) Law 3937 of 15 March 2011 on Biodiversity and other Aspects of Conservation.
([100]) XXXIII Law on Patents and Protection of Inventions (1995)
([101]) XXI Law on the Protection of Human Genetic Data, on the Rules of Human Genetic Testing and Research and the Operation of Biobanks (2008)
([102]) LXXIX Law on the Protection of Foetal Life (1992)

instances where genetic counselling is made available especially to women during pregnancy and before a pregnancy ([103]).

GMOs

Under Hungary's Basic Law, Article XX, Hungary can enforce the right to physical and mental health by assisting agriculture with GMOs ([104]). The XXVII Law on Genetic Engineering (1998) is a standard GMO law which provides for the licencing and regulation of contained use of GMOs ([105]), deliberate release of GMOs and placing GMOs or GMO products on the market. It further, specifies safety requirements, import, transport and transit permit requirements and risk assessments and reporting obligations on users of GMOs.

Criminal context

The LXVI Law on the Registration of Citizen's Personal Data and Address (1992) provides for DNA procedures in criminal context ([106]). It specifies when DNA samples can be taken from suspects or convicted persons, how and when DNA samples must be registered and how DNA can be shared with other EU countries. The Law also provides for how long DNA is kept in the database and how it is to be stored.

Environmental laws, agriculture and food safety

The CXIV Law on Livestock Breeding (1993) regulates the quality of livestock ([107]). It provides that the genetic information of livestock must be of marketable quality. The statute also aims to promote genetic diversity in livestock. It also provides for the protection of endangered species and their genetic information.

The LII Law on the Protection of Nature (1996) regulates the protection of nature ([108]). It forbids the artificially modification of the genetic stock of wild animals. It also specifies that it is forbidden to import genetically modified organisms and introduce them into the wild without appropriate authorisations.

3.14 Iceland

General Outline

Laws of Iceland provide a comprehensive coverage of issues relating to genetics and cover topics such as insurance, privacy law, inheritance, animal welfare, DNA police database, IVF and use of embryos for stem cell research as well as GMOs, Patents and Food Safety. The most significant legislation is the Law on Artificial Fertilisation and the Use of Human Embryos and Embryos for Stem Cell Research (1996). Interesting outliers are the laws on inheritance whereby falsely claiming a genetic relationship with someone for the purpose of claiming their inheritance is an offence according to the Law Inheritance (1962).

([103]) CLIV Law on Health (1997)
([104]) Hungary's Basic Law
([105]) XXVII Law on Genetic Engineering (1998)
([106]) LXVI Law on the Registration of Citizen's Personal Data and Address (1992)
([107]) CXIV Law on Livestock Breeding (1993)
([108]) LIII Law on the Protection of Nature (1996)

The most relevant legislation: Law on Artificial Fertilisation and the Use of Human Embryos and Embryos for Stem Cell Research (1996)

Health laws and embryo research

The Law on Counselling and Education Regarding Sex, Childbirth and on Abortion and Sterilisation (1975) provides as one of the reasons for abortion when the foetus is at risk of serious genetic diseases and that abortion should always be allowed after the standard 16 weeks if there is a high probability of genetic defects in the foetus ([109]). The Law further provides that sterilisation of a person is allowed when the person's children would be at a high risk of a genetic disease.

The Law on Artificial Fertilisation and the Use of Human Embryos and Embryos for Stem Cell Research (1996) provides that in cases where there is a risk of severe genetic diseases, the use of donor cells is permitted in IVF; and cells intended to be used for IVF cannot be destroyed ([110]). Embryos may be used for research in certain circumstances when they are not intended for IVF and the research would yield useful scientific and medical knowledge, but all projects must be permitted by the Bioethics Committee. It must also be shown that there is no other way to conduct the research. It is prohibited to cultivate or produce embryos solely for research purposes and have embryos for more than 14 days outside the body or once the primitive streak has developed. It is also prohibited to perform nuclear transfer for reproductive purposes (cloning) and transplant human embryos into animals.

Patents

The Patent Act (1991) is a standard European legislation relating to patents with essentially identical prohibitions on patentability as most of the jurisdictions above and below ([111]). The Act prohibits patents for methods of cloning humans, modifying the human germ line, commercial uses for human embryos and changing animal genes without a substantial medical benefit to humans or animals.

Other

The Law on Inheritance (1962) brings genetics into the context of inheritance and Article 25 creates a criminal offence for where a person fraudulently claims to be in a genetic relationship in order to get their inheritance ([112]). The Law on Insurance Contracts (2004) prohibits companies to use results of genetic testing and any associated risks of developing certain diseases to determine the insurance policy of clients, nor are companies allowed to request such information ([113]).

Privacy and data protection

The Privacy Act (2000) specifies genetic information as sensitive personal information and hence all provisions governing the handling ([114]), storage and access to sensitive personal information govern genetic information and this information is afforded the highest level of protection by the law.

([109]) Law on Counselling and Education Regarding Sex and Childbirth and on Abortion and Sterilisation (1975)
([110]) Law on Artificial Fertilization and the Use of Human Embryos and Embryos for Stem Cell Research (1996)
([111]) Patent Act (1991)
([112]) Law on Inheritance (1962)
([113]) Law on Insurance Contracts (2004)
([114]) Privacy Act (2000)

Criminal context

The Law on Genetic Register of Police (2001) establishes the Icelandic DNA database for storing and comparing DNA of suspects and convicts ([115]). The Law specifies when and how DNA can be collected, when must it be destroyed, who can have access to the information; and provides that the Data Protection Authority shall ensure proper administration of the database and protect the privacy of the individuals whose information is contained in the database.

GMOs, environmental, agricultural and animal laws

The Law on Import of Animals (1990) provides for import of animal genetic material (eggs and sperm) and provides for regulations on ensuring the health of any imported genetic material.([116]) The Animal Diseases Act and Prevention of Animal Disease (1993) includes prevention of genetic diseases in its aim to prevent animal disease ([117]). The Veterinary and Animal Health Act (1998) regulates the genetic quality of imported livestock and the Law on Animal Welfare (2013) prohibits genetic engineering of animals where it would change the characteristics of the animal in such a way so as to detrimentally affect the animal's health or behaviour as well as their offspring and if it were to reduce the ability of the animal to show 'normal' behaviour ([118]).

The Act on GMOs (1996) is a standard GMO statute and regulates the contained use, deliberate release and marketing of GMOs ([119]). The Act specifies what licences are necessary, what safety measures must be taken and what powers the relevant authorities have to inspect the users of GMOs. The Food Act (1995) gives the Minister the power to issue regulations with respect to packing, labelling, ingredients, internal processes, inspections and packing of genetically modified foods ([120]).

3.15 Ireland

General Outline

There seems to be a notable absence of legislation governing gene editing and research on embryos (see here for an article for more detail). The legislation relating to genetics covers environmental protection, patents, genetic testing, animal welfare and DNA samples in the criminal context as well as data protection.

Most relevant legislation: The Disability Act 2005

Health laws

The Disability Act 2005 governs genetic testing in persons and provides that testing shall not be carried out on a person unless it is not prohibited by law and the consent of the data subject has been obtained in accordance with the Data Protection Act ([121]). The

([115]) Law on Genetic Register of Police (2001)
([116]) Law on the Import of Animals (1990)
([117]) Animal Diseases Act and Prevention of Animal Disease (1993)
([118]) Veterinary and Animal Health Act (1998); Law on Animal Welfare (2013)
([119]) The Act on GMOs (1996)
([120]) Food Act (1995)
([121]) Disability Act 2005

subject of the genetic testing must be provided with all relevant information prior to the genetic sample being collected.

Patents

The Patents Act 1992 seems substantially different to many of the other patent statutes in this report ([122]). The Act does not specifically refer to genetics or other genetic-related issues, but the Act would nonetheless be relevant and shows the potential gaps in legislation where genetics are not specifically addressed.

Criminal context

Criminal Justice (Forensic Evidence and DNA Database System) 2014 establishes the DNA database ([123]), as well as the framework for when DNA samples can be taken from suspects and the procedures for collection, storage and handling of the samples and any resulting data.

GMOs, environmental and animal laws

The Environmental Protection Agency Act 1992 gives the Minister power to issue regulations relating to GMOs and such regulations have been issued (S.I. No 500/2003 Genetically Modified Organisms (Deliberate Release) Regulations 2003 ([124]).

The Animal Health and Welfare Act 2013 provides that the Minister may direct that an animal may be killed or destroyed where the Minister is of the opinion that it is because of its genetic makeup particularly susceptible to disease ([125]).

Data protection

The Data Protection Act 2018 provides for the protection of personal data which includes genetic data and which is subject to a high protection level because it is specified as a special category of data ([126]).

3.16 Italy

General Outline

The laws of Italy relating to genetics are fairly varied, but only few of the available instruments engage with the subject deeply. Many of the located laws relate to agriculture and implementation of international agreements. There are laws govern the protection of privacy, as well as the use of embryos in research and the protection of the environment and GMOs. It is highly likely that many of the criminal and GMO-related provisions are included in regional regulations and hence outside of the scope of this review.

([122]) Patents Act 1992
([123]) Criminal Justice (Forensic Evidence and DNA Database System) 2014
([124]) Environmental Protection Agency Act 1992
([125]) Animal Health and Welfare Act 2013
([126]) Data Protection Act 2018

Most relevant legislation: Law of 19th February 2004 n 40 – Rules on medically assisted reproduction

Embryo research

The Law of 19th February 2004 n 40 – Rules on Medically Assisted Procreation provides that couples with genetically transmissible diseases can utilise IVF ([127]). It is prohibited to engage in behaviour which may lead to cloning a person and this act is punishable by 10-20 years in prison and a substantial monetary penalty. As per Article 13, experimentation on embryos is forbidden, any form of eugenic selections of embryos or gametes through any techniques aimed at altering the genetic information of the embryo or gamete or 'designing' the genetic characteristics of an embryo is also forbidden. Note that Article 13 has been updated by a constitutional court decision (Sentenza 21 October – 11 November 2015, n.229 published in Gazzetta Ufficiale, 1ª Serie Speciale n. 46 of 18/11/2015,) which allows for selection of embryos in situations where the selection of an embryo is targeted at avoiding or preventing implantation of an embryo which is affected by a genetically transmitted disease.

Data protection

The Code for the Protection of Personal Data (2003) includes genetics as personal data and provide how a person consents ([128]), must be informed and when notifications are necessary when the genetic data is being used. There is a special provision on the handling of genetic data of bone marrow donors.

GMOs, agriculture and environment

The Law of 22nd November 2004, n. 279 – Urgent provisions to ensure coexistence between the forms of transgenic, conventional and biological agriculture, provides for how transgenic crops can co-exist with standard crops ([129]). The Environmental rules – Legislative Decree of 3 April 2006, no 152 (note this is often referred to as the Environmental Code but is not formally a code) identify uses for GMOs in protecting the environment, including the use of GMOs to improve the soil ([130]). The Law of 1st December 2015, n 194 – Provisions for the protection and enhancement of biodiversity of agricultural and food interests aims to protect agriculture and food sources from genetic pollution and loss of genetic heritage ([131]). It specifies which organisms are local and establishes networks to support the development of the local agricultural resources.

Other

Many of the listed laws contained in the individual jurisdiction report relate to Italy's implementation of international agreements; these include the implementation of the Biodiversity Convention, the Cartagena Protocol, International Resource Treaty on Phytogenetics and the European Convention for the Protection of Minors Against Sexual Exploitation and Abuse ([132]).

([127]) Law of 19th February 2004, n 40 – Rules on medically assisted procreation
([128]) Code for the Protection of Personal Data (2003)
([129]) Law of 22nd November 2004, n 279 – Urgent provisions to ensure coexistence between the forms of transgenic, conventional and biological agriculture
([130]) Environmental rules – Legislative Decree of 3 April 2006, no 152
([131]) Law of 1st December 2015, n 194 – Provisions for the protection and enhancement of biodiversity of agricultural and food interests
([132]) Law of 14th February 1994 n. 124 – Ratification and implementation of the biodiversity convention, with annexes made in Rio de Janeiro on 5 June 1992; Law of 15th January 2004, n. 27 – Ratification and implementation of the Cartagena Protocol on prevention of biotechnological risks related to the Diversity Convention with appendices adopted in Montreal on 29 January 2000; Law of 6 April 2004, n.

3.17 Latvia

General Outline

The laws of Latvia on the genome are sophisticated and engage with the subject. Latvia has one of the most directly targeted legislations on the topic, the Human Genome Research Law which establishes a comprehensive legislative framework for governance of genetics research in the country. There are also laws on the environment, criminal procedure, sexual health, environmental protection and GMOs which engage with genetics.

Most relevant legislation: Human Genome Research Law (2003)

Genome research and health law

The Sexual and Reproductive Health Law (2002) regulates IVF and provides when and how it is available; and it also specifies the rights of donors ([133]). The Law prohibits cloning of humans.

The Human Genome Research Law (2003) is perhaps the most comprehensive legislation located throughout the review ([134]). Its purpose is to regulate the establishment and operation of a single genome database of the Latvian population for genetic research and ensures the voluntary nature and confidentiality of gene donation. The Law establishes the Genome Research Board which has the authority to examine projects and concepts related to genetic research, and facilitate provision of public information about such research. There are strict limits on which bodies are allowed to process genetic information contained in the database and register. Genetic research is, as per section 8, permitted for the purpose of studying and describing the mutual connection between genes, human state of health and physical and social environment in order to discover disease diagnostic and treatment methods that will help to assess the health risks of individuals and prevent the causes of diseases.

As per the Human Genome Research Law (2003) the Cabinet shall publish regulations specifying the procedures for genetic research. All processing of information in the database shall be subject to the provisions for processing of personal data. Donors of genetic information must consent to the use of their information in a particular way and have the right to be informed of all the information produced as a result of processing of their genetic data. It is only permitted to use the genome database for scientific research, research and treatment of the diseases of a gene donor, research of the health of society and for statistical purposes. It is prohibited to use the genome database for any other purpose. The Law provides for how information is to be coded and de-identified during research. All research projects must comply with principles of ethics published by the Central Medical Ethics Committee which shall evaluate compliance with those principles in all projects relating to genetics research.

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101 – Ratification and implementation of the international resource treaty phytogenetics for food and agriculture, with appendices adopted by the thirty-first meeting of the FAO Conference in Rome on 3 November 2001

([133]) Sexual and Reproductive Health Law (2002)

([134]) Human Genome Research Law (2003)

Patents

The Patent Law (2007) is a standard patent legislation, which is essentially the same as the patent laws above and below ([135]). The Law as per section 10 prohibits human cloning, modification of the genetic identity of human beings and their germ line, utilisation of human embryos for industrial or commercial purposes and methods for modifying the genetic identity of animals likely to cause them suffering without any substantial medical benefit to people or animals. Furthermore, a human body in different stages of formation and development and a simple discovery of one of its elements, including the sequence or partial sequence of a gene, may not be a patented invention. An element which has been isolated from the human body or otherwise acquired with a technical method, including the sequence or a partial sequence of a gene, may not be a patented invention.

Criminal context

The Law on Development and Use of National DNA Database (2004) establishes a national DNA database to record criminal offences; the Law also regulates the exchange of the results of DNA genetic analysis with other States and international organisations ([136]). The Law prohibits discrimination against persons based on their genetic characteristics. The Law specifies when DNA can be collected from suspects, convict and other persons and when such profiles need to be destroyed.

GMOs, Environmental and agricultural laws

The Plant Varieties Protection Law (2002) provides for protection of plant varieties and describes the ways in which varieties may be protected ([137]). The Law on Circulation of Genetically Modified Organisms (2007) is largely a standard GMO legislation regulating the use of GMOs, their release and marketing ([138]). It gives the relevant Minister power to promulgate regulations with respect to GMOs which will contain the finer details of GMO rules on licencing. Interestingly, section 23 prohibits the release of deliberately genetically modified organisms containing genes, with code resistance to antibiotics used in medicine or veterinary uses, if it is determined in the risk assessment of potential effect of gene transfer of the particular genetically modified organism, that they have an adverse effect on human and animal health or the environment.

3.18 Lithuania

General Outline

The Lithuanian laws on genomes are comprehensive and cover a wide variety of topics. The most significant legislation is the Law on Ethics in Biomedical Research (2002). This Law is the most comprehensive legislation on genome research and gene technology use in the surveyed jurisdictions. It sets out when embryos are allowed to be used, where human genomes can be modified and what principles are to be followed in any such research. Lithuanian laws on patents, animals, environment, GMOs as well as criminal procedure also cover genetics.

Most relevant legislation: Law on Ethics in Biomedical Research (2002)

([135]) Patent Law (2007)
([136]) Law on Development and Use of the National DNA Database (2004)
([137]) Plant Varieties Protection Law (2002)
([138]) Law on Circulation of Genetically Modified Organisms (2007)

Patents

The Patent Law (1994) is standard and extremely similar, nigh identical, to other patent statutes above and below in this document ([139]). As per Article 2 it prohibits patents for methods of human cloning, modification of the genetic identity of human beings and their germ line, utilisation of human embryos for industrial or commercial purposes and methods for modifying the genetic identity of animals likely to cause them suffering without any substantial medical benefit to people or animals, as well as animals resulting from such methods.

Health laws and embryo research

The Law on the Rights of Patients and Compensation for the Damage to Their Health (1996) prohibits discrimination or restriction of patient rights based on their genetic characteristics ([140]). The Law on Artificial Fertilisation (2014) prohibits the use of IVF as a means of modifying the identity of the germ line of a person or their offspring ([141]).

The Law on Ethics in Biomedical Research (2002) provides in Article 3 that where human embryos or foetuses are used in biomedical studies ([142]), only those where the benefits are expected to outweigh the risks for the human embryo and human foetus are allowed. It is forbidden to use embryos that have died after a pregnancy termination when there are no medical indications. It is prohibited to carry out studies where the embryo or foetus is destroyed as a result of the study. The law provides further that human cloning is prohibited; and biomedical studies which modify the human genome may only be carried out for the purposes of prevention, diagnosis or treatment and only in cases where they are not intended to modify the progeny genome (the germ line).

According to the Law on Ethics in Biomedical Research (2002), per Article 4, it is prohibited to discriminate against a person or restrict his or her rights or legitimate interest based on results of the genetic studies. Article 5 provides the ethical requirements for biomedical research which must be followed at all times. The Law specifies that consent is necessary for participation in research; and consent is also crucial for an individual's information to be stored in a biobank. The Law regulates the establishment, running and obligations of biobanks as well as the protection of all genetic information.

Criminal context

The Police Law (2000) authorises relevant officials to take samples of genetic material without consent for comparative study and identification purposes ([143]). The Law on the Approval, Entry into Effect and Implementation of Criminal Procedure (2002) provides when suspects' genetic information can be taken, despite the lack of consent of the suspect.

GMOs, animal, environmental and agricultural laws

([139]) Patent Law (1994)
([140]) Law on the Rights of Patients and Compensation for the Damage to Their Health (1996)
([141]) Law on Artificial Fertilisation (2014)
([142]) Law on Ethics in Biomedical Research (2002)
([143]) Police Law (2000)

The Law on Animal Welfare and Protection (1997) prohibits raising of genetically defective animals or pets with obvious genetic diseases, malformations or pathologies ([144]). It is also prohibited to exhibit genetically defective pets with the same defects.

The Law on Advertising (2000) provides that food containing GMOs must be so labelled and labelled in line with the latest regulations, issued under the authority of this Law ([145]). The Law on Genetically Modified Organisms (2001) is a standard GMO statute which sets up the regulatory regime for genetically modified organisms ([146]). The Law provides regulations on the contained use, deliberate release and marketing of GMOs and GMO products and specifies the licensing procedures, related safety measures and gives the Ministry of the Environment the authority to establish and manage a database of all GMOs and GMO products. The Law also contains offence and liability provisions for users who breach any provisions of the Law. The Environmental Protection State Controls Law (2002) provides that the state authorities shall control the limited use of GMOs and their release into the environment in accordance with the law ([147]).

The Plant National Genetic Resources Law (2001) regulates plant genetic resources and stipulates those as the national resources of the Republic of Lithuania and an integral part of the State's living resources ([148].) The Act further specifies how seed and plant genetic material is to be stored, handled and conserved.

Other

The Insurance Law (2003) prohibits insurers taking any genetic data of the potential insured into their calculations in any way ([149]).

3.19 Luxembourg

General Outline

The laws of Luxembourg on the genome are relatively comprehensive but no legislation could be located which covered embryo research or stem cell research. It is possible that such regulation is contained in secondary or local regulations and hence outside of the scope of this review. The most significant legislation located is likely the Health Code which provides for regulations on gene therapy and genetic research.

Most relevant legislation: Health Code

Health laws

The Health Code establishes an ethics committee with respect to gene therapy and genetic research as well as any related clinical trials ([150]). The Code specifies how sensitive data, including genetic data, are to be handled, stored and destroyed. The Code

([144]) Law on Animal Welfare and Protection (1997)
([145]) Law on Advertising (2000)
([146]) Law on Genetically Modified Organisms (2001)
([147]) Environmental Protection State Controls Law (2002)
([148]) Plant National Genetic Resources Law (2001)
([149]) Insurance Law (2003)
([150]) Health Code

further provides for rules on the behaviour of inspectors whose duties include inspecting GMOs in medicines.

Criminal context

The Penal Code provides for the use of DNA in the context of criminal proceedings ([151]). It specifies when DNA samples can be collected from suspects or convicts and the exact procedure of doing so. It provides for the protection of all DNA data collected and how the samples are to be stored and handled. Law of 25 August 2006 on DNA identification procedures in criminal matters and the amending Code of Criminal procedure specifies some further details to the Penal Code.

Patents

The updated Law of 7 April Amending the Amended Law of 20 July 1992 Amending the Patent System, is typical of patent legislation, as seen in numerous legislations above ([152]).

GMOs and agricultural laws

The Law of 13 January 1997 on the Control of the Use and Dissemination of Genetically Modified Organisms is another standard GMO legislation which regulates the contained use, deliberate release and marketing of GMOs ([153]). The Law provides for procedures for licensing, safety measures and requirements as well as reporting obligations and associated liabilities and penalty provisions.

The Law of 18 March 2008 on the marketing of seeds and seedlings and the coexistence of genetically modified, conventional and organic crops provides for how GMO crops and seeds can coexist and be marketed on the same market ([154]). Similarly, Law of 17 November 2017 on the marketing of fruit plant propagating material and fruit plants intended for the production of fruit does so for genetically modified fruit and the Law specifies that any GMO fruit must be so labelled ([155]).

Data protection

The Law of 2 August 2002 on the Protection of Individuals with regard to the Processing of Personal Data provides for security protections of genetic data classified as health data, which is subject to higher protection than other kinds of data ([156]).

Other

The Law of 27 July 1997 on the Insurance Contract prohibits use of genetic information in the insurance context, as several laws in jurisdictions above have done ([157]).

([151]) Penal Code
([152]) Law of 7 April 2006 amending the amended Law of 20 July 1992 amending the patent system
([153]) Law of 13 January 1997 on the control of the use and dissemination of genetically modified organisms
([154]) Law of 18 March 2008 on the marketing of seeds and seedlings and the coexistence of genetically modified, conventional and organic crops
([155]) Law of 17 November 2017 on the marketing of fruit plant propagating material and fruit plants intended for the production of fruit
([156]) Law of 2 August 2002 on the protection of individuals with regard to the processing of personal data
([157]) Law of 27 July 1997 on the insurance contract

3.20 Malta

General Outline

Laws of Malta on the genome are comprehensive and cover many topics, including environmental protection, GMOs, animal welfare, food safety, patents and genetic testing. The most significant legislation is the Embryo Protection Act (2013), which prohibits sex-selection of embryos and altering of the human germ line.

Most relevant legislation: Embryo Protection Act (2013)

Patents

The Patents and Designs Act (2002) is another standard patent statute which ([158]), as per section 4, prohibits patents for methods of human cloning, modification of the genetic identity of human beings and their germ line, utilisation of human embryos for industrial or commercial purposes and methods for modifying the genetic identity of animals likely to cause them suffering without any substantial medical benefit to people or animals. It also specifies that Patents shall not be granted in respect of the human body including the sequence or partial sequence of a gene. An element isolated from the human body by means of a technical process, including the sequence of a gene, may constitute a patentable invention.

Health laws and embryo research

The Clinical Trials Regulations (2004) specify that the Ethics Committee must supervise and approve all clinical trials and may get an extension on its decision time if the drugs or therapies under consideration are gene therapies or contain genetically modified organisms ([159]).

The Embryo Protection Act (2013) prohibits the selection of embryos based on the presence or absence of a sex-chromosome, except where it is done to prevent the occurrence of a sex-linked genetic illness ([160]). Section 11 of the Act prohibits any acts and interventions seeking to clone human beings. Section 13 specifies that it is a criminal offence punishable by imprisonment and a substantial fine to alter in an artificial way the genetic information of a human germ line; it is also an offence to knowingly use such a cell. It is not an offence if a medical practitioner does any of these acts as unintended consequences of inoculation, radiation or chemotherapeutic treatment. It is further an offence to unite embryos with different genetic material to a cell conglomerate using at least one human embryo. It is also an offence to join a human embryo with a cell that contains genetic information different from the embryo cells and induces them to develop further.

Criminal context

The Criminal Code (1854) specifies who can collect DNA in criminal proceedings and when DNA can be transmitted outside Malta ([161]).

([158]) Patents and Designs Act (2002)
([159]) Clinical Trials Regulations (2004)
([160]) Embryo Protection Act (2013)
([161]) Criminal Code (1854)

GMOs, animal and environmental laws

The Animal Welfare Act (2002) specifies that only persons with a licence by the Minister ([162]), acting on the advice of the Council and the Director of Veterinary Services, may carry out the alteration of the genetic material of animals in a manner which ignores the natural barriers of sexual reproduction and recombination. The Environmental Protection Act (2016) specifies that the Minister may make regulations with respect to access to genetic resources ([163]).

The Food Safety Act (2002) establishes the Food Safety Commission which has as one of its functions to regulate and oversee the safety of GMO foods ([164]). The Act also gives the Minister the power to make regulations with respect of GMO foods. The Contained Use of Genetically Modified Micro-Organisms Regulations (2008) and the Deliberate Release into the Environment of Genetically Modified Organisms Regulations (2010) are standard GMO legislative instruments which provide for the contained use, deliberate release and marketing of GMOs and GMO products ([165]). They also provide for the associated safety measures, licensing procedures and penalties.

Other

The Civil Code (1870) contains several provisions relating to the parentage of a child and disputes about paternity of a child including who is allowed to force a DNA sample to be given and what genetic samples can be used in this context (which is mainly to prove the relationship between persons) ([166]). The Work-Based Learning and Apprenticeship Act (2018) provides that the training programmes' entry requirements and the selection of students shall be equitable and free from discrimination on the grounds of genetic features ([167]).

3.21 The Netherlands

General Outline

Dutch laws relating to the genome are comprehensive and cover topics of DNA in the context of crime, environmental protection, GMOs, patents, animal laws and embryo research, as well as medical research on humans. The most significant pieces of legislation are likely the Law on Medical Research on Humans of 26 February 1998 and the Embryo Law of 20 June 2002, which directly relate to genetic research and the permitted uses of embryos in research.

Most relevant legislation: Law on Medical Research on Humans of 26 February 1998 and the Embryo Law of 20 June 2002

Health laws and embryo research

([162]) Animal Welfare Act (2002)
([163]) Environment Protection Act (2016)
([164]) Food Safety Act (2002)
([165]) Contained Use of Genetically Modified Micro-Organisms Regulations (2008); Deliberate Release into the Environment of Genetically Modified Organisms Regulations (2010)
([166]) Civil Code (1870)
([167]) Work-Based Learning and Apprenticeship Act (2018)

The Law on Medical Research on Humans of 26 February 1998 regulates medical research on humans ([168]). It specifies how gene therapies are to be researched and it forbids experimentations on humans in a way that changes the germ line of humans.

The Embryo Law of 20 June 2002 forbids all actions involving germ cells or embryos with a view to the birth of a genetically identical human being ([169]), or to deliberately modify the genetic material of the nucleus of human germ cells which might establish a pregnancy.

Patents

The Patent Act of 15 December 1994 is a standard patents statute which, according to Article 3 ([170]), prohibits patents for methods of human cloning, modification of the genetic identity of human beings and their germ line, utilisation of human embryos for industrial or commercial purposes and methods for modifying the genetic identity of animals likely to cause them suffering without any substantial medical benefit to people or animals, as well as animals resulting from such methods.

Criminal context

The Code of Criminal Procedure of 15 January 1921 provides for when DNA samples can be taken with and without consent from suspects ([171]) and specifies the collection procedure, handling and analysis of all DNA samples in the context of a criminal investigation and/or proceeding. Law on DNA and Convicted Persons of 16 September 2004 provides further details on how DNA analysis is to be carried out in the context of a criminal proceeding and specifies when collections of DNA samples are allowed ([172]).

GMOs, Environmental and animal laws

Law on Animal Testing of 12 January 1977 provides when animal experiments end with regards to genetically modified animal lines ([173]). The Animal Law of 19 May 2011 forbids changing genetic material of animals solely for the purpose of enhancing their sporting performance or entertainment in a manner that ignores the natural barriers of sexual reproduction and recombination ([174]). It also prohibits the use of biotechnological techniques on animal or animal embryos without a permit.

The Law on Environmental Conservation of 13 June 1979 establishes the Genetic Modification Committee ([175]), which advises the Minister on applications for authorisations for the use of GMOs. The Law provides how licences can be obtained for the contained use of GMOs, their deliberate release and marketing. It further specifies the relevant safety requirements and ongoing obligations of licensees. The Law also regulates the appropriate packaging and labelling of GMOs and GMO products. The Seed and Planting Materials Law of 19 February 2005 mandates that trading in seeds must be done with genetic diversity in mind ([176]), but exemptions for GMOs can be granted by the Minister.

([168]) Law on Medical Research on Humans of 26 February 1998
([169]) Embryo Law of 20 June 2002
([170]) Patent Act of 15 December 1994
([171]) Code of Criminal Procedure of 15 January 1921
([172]) Law on DNA and Convicted Persons of 16 September 2004
([173]) Law on Animal Testing of 12 January 1977
([174]) Animal Law of 19 May 2011
([175]) Law on Environmental Conservation of 13 June 1979
([176]) Seed and Planting Materials Law of 19 February 2005

3.22 Norway

General Outline

Norwegian laws related to genetics are comprehensive and cover varied topics, including environmental protection, animal laws, patent as well as GMOs. The most crucial legislative instruments are the Act on Human Medicine Use of Biotechnology, etc. (Biotechnology Act) (2003) and the Law on Treatment Biobanks (Treatment Biobank Act) (2003) which regulate how research on embryos is performed and what genetic research is permitted.

Most relevant legislation: The Act on Human Medicine Use of Biotechnology, etc. (Biotechnology Act) (2003) and the Law on Treatment Biobanks (Treatment Biobank Act) (2003)

Health law and biotechnology

The Act on Human Medicine Use of Biotechnology, etc. (Biotechnology Act) (2003) regulates when genetic studies and gene therapy courses can be implemented. It further prohibits genetic modification of frozen eggs which are later use in IVF ([177]). The law also regulates when fertilised eggs may be used for research; prohibits research that causes genetic changes which may be inherited in humans; and prohibits production of embryos by cloning. The Law also outlines the circumstances when genetic counselling or 'guidance' should be given to the woman or couple expecting a child. The Act also provides when and how genetic analysis and/or studies can be conducted on individuals; and who is allowed access to genetic information.

The Law on Treatment Biobanks (Treatment Biobank Act) (2003) provides what consent is necessary and under what circumstances may people access the information in a biobank ([178]). The Law also specifies the procedure via which information is deposited in a biobank.

Patents

The Patent Act (1967) appears to be the standard patent statute seen in many instances above and below in this report.([179]) Sections 1, 1a, 1b and 3a prohibit patents for methods of human cloning, modification of the genetic identity of human beings and their germline, utilisation of human embryos for industrial or commercial purposes and methods for modifying the genetic identity of animals likely to cause them suffering without any substantial medical benefit to people or animals as well as animals resulting from such methods.

GMOs, agricultural, environmental and animal laws

The Law on the production and use of genetically modified organisms etc. (Genetic Technology Act) (1993) is a standard GMO statute which regulates the contained use, deliberate release and marketing of GMOs and GMO products ([180]). The Law provides for

([177]) The Act on Human Medicine Use of Biotechnology, etc. (Biotechnology Act) (2003)
([178]) Law on Treatment Biobanks (Treatment Biobank Act) (2003)
([179]) Patent Act (1967)
([180]) Law on the production and use of genetically modified organisms etc. (Genetic Technology Act) (1993)

safety measures, reporting obligations as well as availability of information to the public relating to GMOs.

The Law on Animal Welfare (2009) prohibits breeding in animals using genetic engineering methods ([181]), and the Nature Conservation Act (Nature Diversity Act) (2009) outlines when species are designated as priority species ([182]), and it aims to protect the genetic diversity of animals and plants in the wild. The priority species are afforded special protection status.

3.23 Poland

General Outline

The Polish laws relating to genetics cover several topics, but it must be noted that the website source has limited the ability of the author to locate more. The most relevant law is likely the Act of 22 June 2001 on Microorganisms and genetically modified organisms which regulates the use of genetically modified organisms.

Most relevant legislation: Act of 22 June 2001 on Microorganisms and genetically modified organisms

Patents

The Act of 9 May 2007 about Amending the Act on Copyright and Related Rights and some other Laws (this is the Act's name) ([183]) regulates copyrights and patents and is one of the biggest amendments in the past few decades in this area. There is no specific section covering genes, but the law may still be relevant.

Health laws

The Act of 1 July 2005 on the Collection, Storage and Transplantation of Cells, Tissues and Organs regulates collection, storage and transplantation of cells in humans ([184]). It sets up tissue banks where cells and tissues are to be stored; and details the procedures for confidentiality and safety that are to be followed. It also prohibits certain acts with respect to cells, tissues and organs. It is forbidden to pay for any cells, tissues and organs from donors.

GMOs and environmental protection

Act of 22 June 2001 on Microorganisms and genetically modified organisms is a standard piece of GMO legislation ([185]) which regulates the contained use, deliberate release and marketing of GMOs and GMO products. The Law provides for safety measures, reporting obligations as well as availability of public information relating to GMOs. The Act on Plant Protection provides for special powers of Inspector with respect to GMOs and inspections of crops.([186])

([181]) *Law on Animal Welfare (2009)*
([182]) Nature Conservation Act (Nature Diversity Act) (2009)
([183]) Act of 9 May 2007 about Amending the Act on Copyright and Related Rights and some other Laws
([184]) Act of 1 July 2005 on the Collection, Storage and Transplantation of Cells, Tissues and Organs
([185]) Act of 22 June 2001 on Microorganisms and genetically modified organisms
([186]) Act on Plant Protection

3.24 Portugal

General Outline

The Portuguese laws relating to genetics are comprehensive and cover many topics. The most relevant and notable law is Law no 12/2015 of 26 January on Personal Genetic Information and Health Information, which provides an in-depth regulation of genetic research, storage of genetic information as well as the limits of procedures which can be utilised in working with genetic information. This appears to be one of the most comprehensive pieces of legislation focusing on genetics among the EU jurisdictions.

Most relevant legislation: Law no 12/2015 of 26 January on Personal Genetic Information and Health Information

Health laws and genetic research

The Law no 12/2015 of 26 January on Personal Genetic Information and Health Information creates a comprehensive regulatory framework for genetic research, storage of genetic information as well as the limits of procedures relating to genetic information ([187]). The Law protects the privacy of genetic information and places special protections on the data; for example, it dictates that genetic and health information be treated separately and only persons with the highest levels of access can have access. The Law prohibits the alteration of the human germ line and outlines what a genetic database is and what permissions must be obtained before setting such a database up. The Act has a chapter on genetic testing whereby it limits the availability of testing and provides that informed consent of the patient must be obtained prior to testing. The Law also prohibits discrimination of any person on the basis of their genetic information or the fact that they have a certain genetic disease. Similarly, insurance companies cannot request access to any genetic information nor can they use such information in setting the insurance premiums. Further, genetic testing in employment is prohibited and cannot be used for recruitment purposes, unless there is some risk to a person with special susceptibility.

Human genome research is to follow the general rules on scientific research in the field of health, with additional confidentiality protections. Free access by the scientific community to emerging data on the human genome must be guaranteed. Research on the human genome is subject to approval by the ethics committees of the relevant hospital, university or research institution. Such research cannot be carried out without the informed consent of the subject. The law also regulates the set-up of DNA banks and tissue banks.

The Law no 32/2006 of 26 July on Medically Assisted Procreation regulates all matters related to IVF and embryo research including the limits on genetic manipulation ([188]). It is thereby prohibited to create a human being genetically identical to another human. It is forbidden to sex-select embryos other than for the purpose of preventing a serious sex-linked genetic disease. It is forbidden to use pre-implantation genetic diagnosis for multifactorial diseases where the predictive value of the test is very low. Use of embryos in research is only allowed when the research is expected to be of great benefit to humanity. There are limits on what embryos are allowed to be used for research; one

([187]) Law no 12/2015 of 26 January on Personal Genetic Information and Health Information
([188]) Law no 32/2006 of 26 July on Medically Assisted Procreation

source of embryos is embryos which have been identified in pre-implantation genetic diagnosis as having a severe genetic abnormality. The Law also provides for when pre-implantation genetic diagnosis can be performed.

Criminal context

The Law no 5/2008 of 12 February on the DNA Profile Database – Civil and Criminal Identification regulates and establishes DNA profile database for both criminal and civil litigation ([189]). It regulates how the DNA data is to be stored and handled and what safety measures must be in place and for what purposes can DNA be collected.

Patents

The Industrial Property Code – Law no 36/2003 of 5 March is a standard patent statute, as seen in the majority of the jurisdictions included in this report. Article 53 prohibits patents for methods of human cloning, modification of the genetic identity of human beings and their germ line, utilisation of human embryos for industrial or commercial purposes and methods for modifying the genetic identity of animals likely to cause them suffering without any substantial medical benefit to people or animals as well as animals resulting from such methods. Article 54 provides that the following can be patented, a novel invention which involves an inventive step and is capable of industrial application affecting any element isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene. The structure of that element is identical to that of a natural element, provided that the industrial application of a sequence or a partial sequence of a gene is observed and concretely disclosed in the patent application.

Data protection

The Law no 67/1998 of 26 October on Personal Data Protection Act regulates access to and handling of personal data ([190]); the personal data includes genetic information. Genetic information is classified as sensitive personal information and special procedures must be employed when handling such data. Law no 94/1999 of 16 July on Access to Documents regulates access to official documents and it specifies how documents containing genetic information can be accessed ([191]).

GMOs and environmental laws

The Law no 142/2008 of 24 July for the Conservation of Nature and Biodiversity outlines measures to maintain and protect biodiversity of the environment ([192]).

The Law no 55/2015 of 17 April on the Confined Use of Genetically Modified Microorganisms and Organisms regulates GMOs and their contained use ([193]). It covers the permits, procedures and processes to be employed in connection to GMOs. It is yet another instance of the standard GMO statute.

([189]) Law no 5/2008 of 12 February on the DNA Profile Database – Civil and Criminal Identification
([190]) Law no 67/1998 of 26 October on Personal Data Protection Act
([191]) Law no 94/1999 of 16 July on Access to Documents
([192]) Law no 142/2008 of 24 July for the Conservation of Nature and Biodiversity
([193]) Law no 55/2015 of 17 April on the Confined Use of Genetically Modified Microorganisms and Organisms

3.25 Romania

General Outline

The Romanian laws on genetics are comprehensive and cover topics ranging from DNA databases in criminal procedure, GMOs, animal laws and extensive laws on embryo research as well as the permitted biotechnological techniques.

Most relevant legislation: Civil Code of 17 July 2009 (Law 287/2009)

Health law and embryo research

Civil Code of 17 July 2009 (Law 287/2009) prohibits any medical intervention intended to modify the genetic information of offspring of an individual ([194]), except for the purpose of preventing and/or treating genetic diseases. It further prohibits the creation of genetically identical humans even if one is deceased and prohibits the choosing of the sex of an embryo unless the reason for the choice is to avoid or prevent a genetic disease. The Code further provides that genetic examination can only be undertaken for medical or scientific purposes and must be permitted by law. The identification of a person on the basis of his/her genetic profile may be done only in the course of a civil or criminal judicial procedure or for medical or scientific research (permitted by law).

The Law no. 2 of 8 January 1998 on the procurement and transplantation of human tissues and organs governs when and how transplants are allowed ([195]). The donor must be genetically compatible with the recipient of the tissue or organ.

Criminal context

The Code of Criminal procedure of 1 July 2010 (Law 135/2010) outlines when genetic samples can be taken in the context of criminal proceedings and/or investigation ([196]). The Law no. 76 of 8 April 2008 on the organisation and operation of the National System of Judicial Genetic Data establishes the National System of Judicial Genetic Data and sets out the conditions under which DNA samples can be taken from suspects and convicts; and how the data is to be processed and stored ([197]).

Animal laws

The Law no. 362 of 10 July 2001 for the approval of the Government Emergency Ordinance no. 33/2000 on the financing from the state budget of measures for the protection of the genetic patrimony of animals establishes the legal framework for financing the maintenance and preservation of genetic information of animals.([198]) The Law no. 43 of 11 April 2014 on the protection of animals used for scientific purposes defines 'procedure' as excluding actions leading to the creation or maintenance of a line of genetically modified animals ([199]). This means that the permitted 'procedures' do not include, and thereby prohibit, such procedures which would lead to the creation or maintenance of genetically modified animals.

([194]) Civil Code of 17 July 2009 (Law 287/2009)
([195]) Law no. 2 of 8 January 1998 on the procurement and transplantation of human tissues and organs
([196]) Code of Criminal procedure of 1 July 2010 (Law 135/2010)
([197]) Law no. 76 of 8 April 2008 on the organisation and operation of the National System of Judicial Genetic Data
([198]) Law no. 362 of 10 July 2001 for the approval of the Government Emergency Ordinance no. 33/2000 on the financing from the state budget of measures for the protection of the genetic patrimony of animals
([199]) Law no. 43 of 11 April 2014 on the protection of animals used for scientific purposes

The Law no. 72 of 16 January 2002 on biological techniques provides that embryo transfer biotechnologies and experimental genetic manipulation are allowed to be used in institutes of scientific research and higher education ([200]), but need to be carried out under the control of the Ministry of Agriculture and Rural Development. The law regulates the import and export of animals' genetic resources and specifies that the genetic improvement of animals should be carried out by selective breeding and hybridisation.

GMOs

Law no. 214 of 19 April 2002 for the approval of the Government Ordinance no. 49/2000 on the regime for obtaining, testing, use and commercialisation of genetically modified organisms through the modern biotechnology techniques, as well as the products resulting therefrom regulates the production, testing, use and commercialisation of genetically modified organism and outlines the regulations especially with respect to contained and uncontained use of genetically modified organisms ([201]). Together with Law no. 3 of 9 January 2008 for the approval of Government Emergency Ordinance no. 44/2007 on the contained use of genetically modified micro-organisms and the Law no. 247 of 30 June 2009 for the approval of Government Emergency Ordinance no. 43/2007 on the deliberate introduction into the environment and on the placing on the market of genetically modified organisms, these statutes appear to be a standard GMO legislation ([202]). They cover the permits, procedures and processes to be employed in connection to GMOs.

3.26 Slovakia

General Outline

There does not appear to be specific legislation on gene technologies and/or research. The Slovakian legislation which relates to genetics covers abortion, environmental protection, animal welfare, patents, GMOs, criminal offences and data protection.

Most relevant legislation: Patent Law 435/2001

Health laws

Law on abortion 73/1986 permits an abortion where there is a genetic abnormality in the foetus.

Patents

The Patent Law 435/2001 is a standard patents legislation and section 6 prohibits patents for methods of human cloning ([203]), modification of the genetic identity of human beings and their germ line, utilisation of human embryos for industrial or commercial purposes

([200]) Law no. 72 of 16 January 2002 on biological techniques

([201]) Law no. 214 of 19 April 2002 for the approval of the Government Ordinance no. 49/2000 on the regime for obtaining, testing, use and commercialisation of genetically modified organisms through the modern biotechnology techniques, as well as the products resulting therefrom

([202]) Law no. 3 of 9 January 2008 for the approval of Government Emergency Ordinance no. 44/2007 on the contained use of genetically modified micro-organisms; Law no. 247 of 30 June 2009 for the approval of Government Emergency Ordinance no. 43/2007 on the deliberate introduction into the environment and on the placing on the market of genetically modified organisms

([203]) Patent Law 435/2001

and methods for modifying the genetic identity of animals likely to cause them suffering without any substantial medical benefit to people or animals, as well as animals resulting from such methods.

Data protection

Law on the protection of personal data 18/2018 includes genetic information in personal data and genetic data is thus afforded a higher level of protection; and persons must give their consent for their genetic information to be processed, as per section 16 ([204]).

GMOs, environmental, animal and agricultural laws

The Law on the protection of plant genetic resources for agriculture 215/2001 aims to protect the genetic resources of plants for agriculture ([205]). The Law specifies that all genetic resources of plants in the territory of Slovakia are the natural heritage of the Republic. The law sets up storage facilities for the genetic resources of seeds and plants which are deemed important for agriculture and the safety of the foods supply. Law on protection of nature 543/2002 specifies as one of the factors for consideration when deciding which species are endangered, is genetic variability ([206]). The Law against animal abuse 246/1992 provides that experiments on animals are to be carried out on animals which are designated for that purpose and suited from a genetic perspective ([207]).

The Law on Genetically Modified Organisms and Genetic Technologies 151/2002 is a standard GMO statute which regulates the contained use, deliberate release and marketing of GMOs and GMO products ([208]). The Law provides for safety measures, reporting obligations as well as availability of public information relating to GMOs.

Criminal context

Criminal Law 300/2005 prohibits the creation of a genetically identical human being to another one alive or dead. It is also an offence to breach the laws relating to GMOs and genetic technologies ([209]).

Other

Workplace law 311/2001 provides that all persons have the right to work and seek employment and shall not be discriminated against based on their characteristics such as their race, sexuality and genetic information ([210]). Similarly, it is forbidden to discriminate against people in the workplace on the basis of their genetics.

3.27 Slovenia

General Outline

([204]) Law on the protection of personal data 18/2018
([205]) Law on the protection of plant genetic resources for agriculture 215/2001
([206]) Law on protection of nature 543/2002
([207]) Law against animal abuse 246/1992
([208]) Law on Genetically Modified Organisms and Genetic Technologies 151/2002
([209]) Criminal Law 300/2005
([210]) Workplace law 311/2001

Slovenian law relating to genetics covers several topics such as environmental protection, but does not appear to have a dedicated legislative instrument for genetic technologies, embryo research and/or biobanks.

Most relevant legislation: Medicines Laws (2014) and Act on the Management of Genetically Modified Organisms (2002)

Criminal context

Law on Police Orders and Authorisations (2013) provides limits on police powers ([211]). It stipulates a principle of equal treatment prohibiting police offices to discriminate against anyone on the grounds of genetic heritage (Art. 14).

Health laws

Medicines Law (2014) regulates medicines and clinical trials ([212]). It specifies that no clinical trials can be conducted where the drug/treatment would change the germ line of the patient. It also provides for special authorisations necessary if a drug trial concerns a gene therapy treatment. The Act on Acquisition and Transplantation of Human Body Parts (2015) regulates transplantations ([213]).

GMOs, environmental, animal and agricultural laws

The Nature Conservation Act (1999) regulates conservation of nature and it specifies biodiversity as a measure of genetic diversity in populations of animals and plants in the wild ([214]). It enumerates measures to maintain and promote such diversity. The Law on Agriculture (2008) regulates agriculture and contains provisions intended to secure genetic diversity of crops and the like ([215]).

The Law on Animal Husbandry (2002) regulates the breeding of animals and also covers aspects of experimentation on animals ([216]). It specifies which genetic modifications are permissible and which are not. It also emphasises that one of the purposes of the law is to maintain genetic diversity in animals, especially in livestock.

The Act on the Management of Genetically Modified Organisms (2002) covers GMOs, their use in food, feed as well as the required safety procedures and permits for placing any GMO products on the market or releasing them into the environment ([217]). It appears to be a standard GMO legislation, which is very similar to the other GMO legislations in this report.

3.28 Spain

General Outline

([211]) Law on Police Orders and Authorisations (2013)
([212]) Medicines Law (2014)
([213]) Transplantation of Human Body Parts (2015)
([214]) Nature Conservation Act (1999)
([215]) Law on Agriculture (2008)
([216]) Law on Animal Husbandry (2002)
([217]) The Act on the Management of Genetically Modified Organisms (2002)

Spanish laws relating to genetics cover a wide array of topics, but the most significant legislative instrument is the Health Code. The Code incorporates a large number of individual laws, including the law on Biobanks and the law on Biomedical Research.

Most relevant legislation: Health Code and a selection of the individual enactment thereby contained

Criminal context

The Penal Code and complementary legislation provides for when DNA samples can be taken for suspects and convicts; and outlines the procedures for collecting, storing and destroying DNA ([218]). The Code creates several offences relating to genetic information modification. Genetic modification in humans is prohibited for all purposes, except for those where the aim is to eliminate or reduce defect or serious disease. Breach of this provision carries a prison sentence. As per section 160, the use of genetic engineering to produce biological weapons is prohibited and punishable by imprisonment. It is prohibited to fertilise human eggs for any other purpose than for human reproduction; this provision carries a custodial sentence. The creation of genetically-identical humans (clones) is prohibited and will be punished by imprisonment.

Health laws

The Health Code specifies when genetic counselling is to be provided to individuals; and mandates that personal data, including genetic data, and the identity of donors of organs must remain secret ([219]). The Code also contains laws 9/2003 and 178/2004 on the Use of Genetically Modified organisms which are the standard GMO legislation that regulate the contained use, deliberate release and marketing of GMOs and GMO products ([220]). The Law provides for safety measures, reporting obligations as well as availability of public information relating to GMOs.

The Code further incorporates the Law 14/2006 of 26 May on Assisted Reproduction, which includes very serious penalties including those for sex selection or genetic manipulation for non-therapeutic or non-authorised therapeutic purposes ([221]). Another very serious penalty is attached to the production of interspecific hybrids that use human genetic material, except in cases of permitted scientific research

The Code also and importantly includes the Law 14/2007 of 3 July on Biomedical Research whereby one of the purposes of the law is to regulate the procedures of genetic analysis and the storage and handling of genetic data ([222]). It is prohibited to discriminate against any person because of their genetic characteristics, or due to their refusal to undergo a genetic analysis or to participate in genetic research. The law specifies what information must be provided to subjects and what consent must be acquired by the scientist.

([218]) Penal Code and complementary legislation
([219]) Health Code
([220]) Law 9/2003 Use of Genetically Modified Organisms; Royal Decree 178/2004 – Regulations under the Law on the Use of Genetically Modified Organisms
([221]) Law 14/2006 of 26 May on Assisted Reproduction
([222]) Law 14/2007 of 3 July on Biomedical Research

The Code includes a Royal Decree 1716/2011 of 18 November on Biobanks, biological samples and the National Registry of Biobanks, which specifies that consent is needed to store, use or access any biological information in the biobank ([223]).

Patents

Law 10/2002 of 29 April which modifies Law 11/1986 on patents for the incorporation into Spanish Law of Directive 98/44 EX, of the European Parliament and of the Council of 6 July concerning the legal protection of biotechnological inventions ([224]). This Law appears to be standard patent statute as seen in many places in this report.

Environmental laws

The Law 42/2007 of 13 December on Natural Heritage and Biodiversity establishes the Spanish Inventory Bank of Genetic Material and provides for the procedures of collecting the materials, storage, access and sharing of genetic materials with other nations ([225]).

3.29 Sweden

General Outline

Swedish legislation provides two statutes which are directly relevant to genetic research, namely the Act on Biobanks in Healthcare, etc. 2002:297 and the Act on Genetic Integrity etc. 2006:351. They outline the details on when embryonic research can be performed and what the limits of genetic research and gene therapy applications are and provide an example of one of the most thorough legislations on this topic. A notable detail is the limit on embryonic research 14 days post-fertilisation and a limit of up to 5 years of freezing eggs; this is similar to the UK legislation and the Portuguese provisions.

Most relevant legislation: Act on Biobanks in Healthcare, etc. 2002:297 and Act on Genetic Integrity etc. 2006:351

Patents

Patent Act 1967 is a standard patents statute, with the addition of prohibiting inventions which are against good practice and morality to be patented ([226]). Section 1 prohibits patents for methods of human cloning, modification of the genetic identity of human beings and their germ line, utilisation of human embryos for industrial or commercial purposes and methods for modifying the genetic identity of animals likely to cause them suffering without any substantial medical benefit to people or animals, as well as animals resulting from such methods.

Health laws and genetic research

([223]) Royal Decree 1716/2011 of 18 November on Biobanks, biological samples and National registry of Biobanks

([224]) Law 10/2002 of 29 April which modifies Law 11/1986 on patents for the incorporation into Spanish Law of Directive 98/44 EX, of the European Parliament and of the Council of 6 July concerning the legal protection of biotechnological inventions

([225]) Law 42/2007 of 13 December on Natural Heritage and Biodiversity

([226]) Patent Act 1967:837

The Act on Biobanks in Healthcare, etc. 2002:297 does not explicitly refer to genes but its topic is closely related and storage of tissues for research can have implications for genetic studies ([227].) The Act on Genetic Integrity etc. 2006:351 is the major legislation in Sweden relating to genetics ([228]). The Act prohibits insurance companies to require or request genetic information from the insured. Sections 3 and 4 (chapter 2) prohibit genetic research, experiments and treatment methods which could lead to genetic changes that could be inherited. The Act also outlines the requirements for the analyses of genetic information in the context of delivering health services or performing scientific research, as well as the conditions in which foetal genetic testing can be done. It provides that research on embryos can be performed if the ethics committee approves the project and the embryo can be used for up to 14 days post fertilisation and limits the time of freezing of eggs/embryos to 5 years. The Act provides details on when IVF is allowed when the woman is not cohabiting with the sperm donor. The Act also provides when gene therapies can be used; and lists penalties for breaching any of the provisions of the Act.

The Pharmaceuticals Act 2015:315 outlines how permissions for clinical trials are granted and provides extended decision periods for cases where the applicant wishes to use a gene therapy drug ([229]).

GMOs, animal and environmental laws

Animal Welfare Act 1988:588 limits when animals may be experimented on and when they can be subject to genetic modification ([230]). The Environmental bar (Code) regulates the use of GMOs ([231]). The statute appears to be fairly standard GMO law similar to many seen above. The Law regulates the contained use, deliberate release and marketing of GMOs and GMO products. The Law provides for safety measures, reporting obligations as well as availability of public information relating to GMOs.

3.30 Switzerland

General Outline

Swiss laws relating to genetics are extremely comprehensive and cover the whole variety of topics which were encountered throughout the review. The Federal Act on Research Involving Embryonic Stem Cells (2003) and Federal Act on Human Genetic Testing (2004) and the Federal Act on Research Involving Human Beings (2011) provide a detailed framework on conducting research on humans, embryos and performing genetic testing. Interestingly, the Swiss constitution itself provides prohibition on cloning and interfering with embryonic cells, which means any significant changes to Swiss laws regarding these topics would require constitutional amendments.

Most relevant legislation: Federal Act on Research Involving Embryonic Stem Cells (2003) and Federal Act on Human Genetic Testing (2004) and the Federal Act on Research Involving Human Beings (2011)

([227]) Act on Biobanks in Healthcare, etc. 2002:297
([228]) Act on Genetic Integrity etc. 2006:351
([229]) Pharmaceuticals Act 2015:315
([230]) Animal Welfare Act 1988:588
([231]) Environmental bar (Code)

Health law, genetic testing and embryo research

Article 119 of the Federal Constitution of the Swiss Federation gives people the right to be protected against the misuse of reproductive medicine and gene technology ([232]). The Confederation shall legislate on the use of human reproductive and genetic material. In doing so, it shall ensure the protection of human dignity, privacy and the family and shall adhere in particular to the following principles – all forms of cloning and interference with the genetic material of human reproductive cells and embryos is unlawful; non-human reproductive and genetic material may neither be introduced into nor combined with human reproductive material; IVF may only be used if there is an infertility issue or a risk of transmitting a serious illness and donation of embryos is unlawful.

The Federal Act on Medically Assisted Reproduction (1998) regulates IVF ([233]). It also restricts analysis of genetic material of reproductive cells and embryos in vitro is to cases where selection of sex or other characteristics is necessary because of a risk that the presence of certain genes will inhibit the developmental capacity of the embryo and when there is no other way of avoiding a serious disease. Genetic counselling must be provided in all cases of genetic analysis of embryos. The Act also regulates how and when reproductive cells can be preserved, namely with the consent of the donor and for a maximum of 5 years and limits the number of embryos developed in the IVF context per woman to a maximum number of twelve. The Act creates an offence for acts whereby a person who in the course of a reproductive technique analyses the genetic material of reproductive cells or embryos in vitro and selects them according to their sex or according to other characteristics, without aiming to overcome infertility or avoid the transmission of the predisposition to a serious disease to the offspring shall be liable to a custodial sentence not exceeding three years or to a monetary penalty.

The Federal Act on Research Involving Embryonic Stem Cells (2003) prohibits a number of acts including the creation of an embryo for research purposes ([234]), the modification of the genetic material in a germ cell, the derivation of embryonic stem cells from an embryo that has undergone germ line modification, or the use of such cells; it is also prohibited to create a clone, chimer or a hybrid. The Act creates serious criminal offences for breaches of any of the prohibited acts listed above.

The Federal Act on Human Genetic Testing (2004) stipulates the conditions under which human genetic testing may be performed in the medical, employment, insurance and liability contexts ([235]). An overriding principle is given in Article 4, whereby no one can be discriminated against on grounds of their genetic characteristics. All genetic testing is to be performed only with the consent of the subject of the test. Genetic tests may only be performed on individuals if they serve a medical purpose and it is forbidden to perform prenatal tests for the purpose of:

- determining the characteristics of the embryo or foetus which do not directly impair its health;

or

- determining the sex of the embryo or foetus for a purpose other than diagnostic.

The Act further outlines extensive privacy and data protection relating to genetic information and any results from genetic processing. The Act prohibits the use of genetic information in the context of insurance and employment. An employer may request an

([232]) Federal Constitution of the Swiss Federation
([233]) Federal Act on Medically Assisted Reproduction (1998)
([234]) Federal Act on Research Involving Embryonic Stem Cells (2003)
([235]) Federal Act on Human Genetic Testing (2004)

employee take a genetic test for pre-symptomatic genetic diseases to prevent occupational diseases and accidents, this exception is narrow and highly regulated.

The Federal Act on Research Involving Human Beings (2011) provides that biological material and genetic data in an un-coded form may be used for research projects if the subject has given informed consent for its use ([236]). The Act also outlines when data can be anonymised.

Patents

Federal Act on Patents for Inventions (1954) seems to be reasonably similar to other patent legislation above but contains more detail ([237]). Article 2 of the Act prohibits patents for processes for cloning human beings; processes for forming hybrid organisms by using human germ cells, human totipotent cells or human embryonic stem cells and the entities obtained thereby; processes of parthenogenesis by using human germinal material and the parthenogenetic entities obtained thereby; processes for modifying the germ line genetic identity of human beings and the germ line cells obtained thereby; unmodified human embryonic stem cells and stem cell lines; the use of human embryos for non-medical purposes and processes for modifying the genetic identity of animals which are likely to cause them suffering without being justified by overriding interests worthy of protection.

The Federal Act on the Promotion of Research and Innovation (2012) does not specifically refer to genetics ([238]), but it is a statute to incentivise and support research in general, presumably including genetic research and applications of such research. It may therefore be relevant.

GMOs and environmental laws

The Federal Act on the Protection of Nature and Cultural Heritage (1966) outlines provisions on sharing genetic resources and incorporates the Nagoya Protocol (concerning sharing of genetic resources internationally) into Swiss law ([239]).

The Federal Act on Non-human Gene Technology (2003) governs the area of GMOs and is fairly similar to the standard GMO legislation which was described many times above ([240]). The Act also establishes the Federal Ethics Committee on non-human biotechnology, which advises on ethical implications of use of GMOs and their handling.

Criminal context

The Swiss Criminal Code stipulates significant sanctions for causing danger in some way using GMOs and foreign nationals shall be expelled by court order if they are convicted of wilfully causing danger by means of GMOs, which is an offence in any case ([241]).

([236]) Federal Act on Research Involving Human Beings (2011)
([237]) Federal Act on Patents for Inventions (1954)
([238]) Federal Act on the Promotion of Research and Innovation (2012)
([239]) Federal Act on the Protection of Nature and Cultural Heritage (1966)
([240]) Federal Act on Non-human Gene Technology (2003)
([241]) Swiss Criminal Code

3.31 United Kingdom

General Outline

The laws of the United Kingdom relating to genetics cover a wide variety of topics ranging from genetics in the criminal context to embryo research and patents. The most significant instruments are Human Tissue Act 2004 and the Human Fertilisation and Embryology Act 1990, with the latter establishing the Human Fertilisation and Embryology Authority which is a body that grants licences to researchers to perform embryonic and related genetic research, thus acting as the main regulator for what research is, and is not, carried out. There has been at least one instance in which a UK research team genetically edited human embryos, which reflects the Authority's willingness to consider such actions for research purposes. See an Article with further detail here.

Most relevant legislation: Human Tissue Act 2004 and the Human Fertilisation and Embryology Act 1990

Health laws and embryo research

The Abortion Act 1967 specifies when abortion is allowed, including if there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped ([242]).

The Human Fertilisation and Embryology Act 1990 is the key legislation in embryo research in the UK ([243]). The Act establishes the Human Fertilisation and Embryology Authority that approves and licences research projects which use human tissue. The Act prohibits a number of acts including the creation of an embryo, except when holding a licence issued by the Authority. Generally speaking, without authorisation, there cannot be any genetic alterations of eggs and sperm and no person shall use modified germ cells to provide fertility services. The Act also provides for prohibitions in connection to genetic material of non-human origin, namely that:

(1) no person shall place in a woman a human admixed embryo, other embryo that is not a human embryo or gametes that are not human gametes;

(2) no person shall mix human gametes with animal gametes, bring about the creation of a human admixed embryo or keep or use such an embryo;

(3) licences cannot authorise the keeping or using of a human admixed embryo after the appearance of the primitive streak or the end of 14 days beginning with the day on which the process of creating the embryo began, and

(4) licences cannot authorise placing human admixed embryos in an animal or keeping or using a human admixed embryo in any circumstances in which regulations prohibit it. Hence there is a hard limit of 14 days for embryonic research from the time of fertilisation. The Act further provides details as to the licence procedure and application, as well as IVF itself.

The Human Tissue Act 2004 does not strictly speaking relate to genetics ([244]), but it can have relevance in research and development of genetic techniques since it governs the

([242]) Abortion (Foetus Protection) Bill 2017-19
([243]) Human Fertilisation and Embryology Act 1990
([244]) Human Tissue Act 2004

handling of human tissues, their collection as well as the required consents and permissions related to those activities.

Patents

The Patents Act 1977 is a standard patent statute, which is essentially identical to most of the patents statutes in the jurisdictions outlined above ([245]). It prohibits the patentability of processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes; processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal.

Criminal context

The Police and Criminal Evidence Act 1984 regulates when DNA profiles can be included on the National DNA Database in the context of criminal investigations and/or proceedings.([246]) The Act specifies when DNA samples and profiles can be destroyed and provides that the National DNA Database Strategy Board must make arrangements for the database operations. It is worth noting that the database had a controversial indefinite retention policy, but the Protection of Freedoms Act 2012 overturned the indefinite retention policy of the DNA database ([247]) in response to the European Court of Human Rights ruling in *S. and Marper versus United Kingdom* (ECHR 1581 - Applications n. 30562/04 and 30566/04). The Protection of Freedoms Act 2012 mainly regulates the use of DNA by the state and is designed to ensure freedoms of citizens and non-citizens to their genetic information.

GMOs, environmental and food laws

The Environmental Protection Act 1990 is the parent Act under which regulations relating to GMOs are promulgated ([248]). The relevant regulations are (1) The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996 and (2) The Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997. The Act provides for general provisions relating to GMO safety and risk assessment, but it is the regulations that contain the detail similar to other GMO statutes mentioned in previous jurisdictions.

The Food Safety Act 1990 provides that the Secretary of State may make regulations with respect to genetically modified foods and GMO foods (foods where their source has been modified by an artificial technique or is derived from genetic material which was so modified) ([249]).

Data protection

The Data Protection Act 2018 regulates the protection of personal data, which includes genetic information ([250]). The Act provides more stringent protections to sensitive processing, which includes the processing of genetic data. The Act also limits the processing of genetic data by insurance providers.

([245]) Patents Act 1977
([246]) Police and Criminal Evidence Act 1984
([247]) Protection of Freedoms Act 2012
([248]) Environmental Protection Act 1990
([249]) Food Safety Act 1990
([250]) Data Protection Act 2018

4 Conclusions

The present report shows that a large body of law exists in the member states of the European Union regarding the implementation of genomics technologies, both supervising the proper handling of the information produced (patents, personal data protection, DNA profiles in forensics, …) and overseeing the new possibilities they offer (genome editing, embryo research, …). The report also highlights similarities and differences between the different regulatory frameworks, when available.

While genomic technologies can be applied in a number of fields, the legislative frameworks across Europe and within member states focus on specific activities, such as genetically-modified organisms (GMOs), embryo research and legislation directly targeting gene editing technologies. Conformity in the legal requirements across the member states in these areas is largely due to legislation implemented at a European level and, in this sense, the European legislation, where present, can be seen as a driving force in the harmonisation of national legislations.

However, maybe because of the absence of an explicit EU legal framework on genomics, there are currently few jurisdictions within Europe which would explicitly allow the potential applications of new genomic technologies, such as CRISPR-Cas9, for gene therapies for serious genetic diseases, due to strict prohibitions on genetic modification of humans. Even in countries where there is no specific prohibition, the situation is often unclear as the relevant legislation does not appear to directly address specific topics, for example non-germ line genetic modifications of humans. This is the case of Malta's Embryo Protection Act (2013), which provides in section 13 that it is a criminal offence punishable by imprisonment and a substantial fine to alter in an artificial way the genetic information of a human germ line. The Act specifies that it is also an offence to knowingly use such a cell. It also, however, specifies that it is not an offence if a medical practitioner does this as an unintended consequence of inoculation, radiation or chemotherapeutic treatment. In short, the Malta's Embryo Protection Act (2013) does not make it clear whether genetic modification which would not affect the germ line could be allowed. The lack of clarity in what is allowed should be resolved by legislators.

With respect to genomic technologies, in particular, the regulatory panorama appears very fragmented and heterogeneous. For example, a number of jurisdictions including the Czech Republic, Luxembourg, Ireland as well as Denmark appear to have no specific legislations addressing them. It is possible that some regulations are in place beyond the primary legislation frame, but lack of such legislation may prove problematic going forward. Another obvious issue is the interaction of the patent laws and genetic research, mainly because many aspects of genetics are not considered patentable, which may create issues for the industry. A wide-ranging debate about what is an appropriate balance is needed before altering the legislations.

With a view to the future, countries should address how to regulate the use of genomic information and the applications of genomic technologies and place clear limits on when they should be allowed. Some applications could have considerable benefits, such as applications which could treat and potentially eradicate serious genetic diseases like Huntington's disease, or use of genomic DNA data in the field of criminal investigations. Other applications are highly controversial, such as elective non-therapeutic altering of embryos that would enable, for example, the possibility to select specific human traits. Even therapeutic uses of genomic information for gene editing purposes give rise to serious ethical questions, which should be addressed before any laws are implemented. Consultation should include inputs from interested stakeholders as well as the public. As the laws stand today, it is possible that in some EU jurisdictions, where there are no clear prohibitions on areas like germ line genetic modifications in humans (see section 'genetics in general' for further details), DNA modification in humans would be legal without much, if any, regulation in place.

4.1 Recommendations

While genes and the transmission of traits from one organism to its offspring have been studied from back two centuries ago, when Mendel studied the hereditary process, using peas, and has been regulated already 20 years ago, genomics is a much younger branch of science. As a matter of fact, from the analysis of the available legal material there are examples of national regulations referring to topics somehow linked to genomics. However, no legislation specifically referring to genomics as such could be identified. The retrieved material, instead, mainly related to different aspects and applications of genetics. For example, terms of reference are "genetic data", "gene manipulation", "genetic material", etc. The "genomic dimension", which is closer to the concept of individual as a whole and distinct entity, is somehow unintentionally missing. One possible explanation is that the most likely first and surely most heavily legislated area in this context in the European Union (and Norway, Iceland and Switzerland) appears to be the use of GMOs, which is clearly written in relation to genetics and not genomics. As a consequence, all the others derive conceptually from the necessity to use genetics as subject.

This implies that while the scientific interests and advancements are at the moment more focused on the structure, function, evolution, mapping, and editing of living organisms' genomes, the available legislation seems to be more related to genes, their variation, and the heredity in living organisms. It would be important to revisit some of these regulatory frameworks in the light of the innovations in genomics technologies, understanding how the current reality matches the letter and intent of the existing laws, and treating and regulating germline and somatic modifications and genomic information as separate issues.

It is important to ensure that potential societal benefits these innovations open are correctly fostered in the regulatory contexts.

More specifically, the laws that would need to be evaluated concern:

1) Human germ line modifications. The first item to be addressed is whether human germ line modifications should be allowed, in view of the new capabilities brought by precision genome editing. If some germ line modifications were allowed, limits on permitted modifications and the purposes for which modifications are allowed should be outlined in the legislative instruments.

2) Non-germ line modifications in humans. Similarly, legislators should evaluate whether non-germ line modifications in humans should be allowed, and if so, what limits should be placed on such modifications.

3) Intellectual and personal rights. Legislators should also consider how the rights of persons having their personal genomic data generated and companies developing gene and genome editing processes and technologies should be protected. At the moment patents statutes across the 31 jurisdictions surveyed for this report prohibit patenting methods for altering the genetic identity of humans. If States wish to encourage the beneficial use of this technology, changes to the patent regime may have to be considered. It is also not clear, in all member states, whether genomics is specifically addressed in personal data protection regulations, and whether they are treated at the same level as other health-related data.

4) Application of gene and genome editing technologies. Besides the above considerations on human applications of gene editing technologies, legislators should also address how to regulate the application of such technologies on animals and plants, especially on species relevant to the food and feed industry.

All the legislative instruments retrieved and compiled for this report is potentially of high interest and importance to all policy makers for their reflections on the available legislative material, but also to international scientific organisations, like the Global Alliance for Genomics and Health, to be able to better frame their research initiatives. An instrument that could provide a public portal to this data, optimally updated as the regulations evolve, would be of high interest.

References

The present report is based solely on the content of national legislations, retrieved by official (when possible) or relevant sources. The references to each piece of legislation are reported within the text. This section reports the main sources used per each country.

Austria:	https://www.ris.bka.gv.at/
Belgium:	http://www.ejustice.just.fgov.be/cgi/welcome.pl
Bulgaria:	https://www.lex.bg/
Croatia:	https://narodne-novine.nn.hr/search.aspx; https://zakon.hr/
Cyprus:	http://www.cylaw.org/
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Finland:	https://finlex.fi/fi/
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Germany:	http://www.buzer.de/; https://www.bgbl.de/
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Iceland:	http://www.althingi.is/lagas/148a/1990054.html
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Netherlands:	http://wetten.overheid.nl/
Norway:	http://www.lovdata.no/
Poland:	http://isap.sejm.gov.pl/
Portugal:	http://www.pgdlisboa.pt/home.php
Romania:	http://legislatie.just.ro/
Slovakia:	https://www.slov-lex.sk/
Slovenia:	http://www.pisrs.si/
Spain:	http://www.boe.es/
Sweden:	http://www.riksdagen.se/sv/dokument-lagar/
Switzerland:	https://www.admin.ch/
United Kingdom:	http://www.legislation.gov.uk/aboutus

List of abbreviations and definitions

Art.:	Article
CRISPR:	Clustered Regularly Interspaced Short Palindromic Repeats
CRISPR-Cas9:	CRISPR-associated protein-9 nuclease
DG:	Directorate General
DNA:	Deoxyribonucleic acid
EC:	European Commission
EEA:	European Economic Area
EEC:	European Economic Community
EMBL:	European Molecular Biology Laboratory
EMBL-EBI:	European Bioinformatics Institute
EU:	European Union
GDPR:	General Data Protection Regulation
GMO:	Genetically modified organism
JRC:	Joint Research Centre
IVF:	In vitro fertilisation
MAR:	Medical Assisted Reproduction
UK:	United Kingdom

List of tables

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KJ-NA-29404-EN-N

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Publications Office

doi:10.2760/04463

ISBN 978-92-79-96740-5