SATORI Deliverable 3.1

Part 1: A report on the legal frameworks that guide or constrain ethical procedures within research within the EU

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1 ABSTRACT

This deliverable comprises a report on the legal frameworks that guide or constrain ethical procedures within research in the EU. It contains two major parts. Part One provides an examination of the legal and regulatory frameworks across 12 domains at the level of the European Union and 8 selected countries. Part Two contains a report that offers an overview of risk analysis approaches in EU legislation and briefly investigates how research and

innovation are taken into account in EU policies, with the final aim of giving insights into the relationship between risk-based regulation on Research and Innovation.

2 EXECUTIVE SUMMARY

This deliverable comprises a report on the legal frameworks that guide or constrain ethical procedures within research within the EU. It contains two major parts. Part one provides an examination of the legal and regulatory framework in the EU and 8 countries (Austria, Germany, France, Poland, Spain, Serbia, UK and the Netherlands) across the following 12 domains:

1. Scientific freedom and freedom of research
2. The right to enjoy the benefits of scientific progress and its application
3. Scientific integrity: codes of conducts and sanctions for scientific misconduct
4. Laws and Regulations on performing ethics assessment
5. Corporate social responsibility
6. Research involving humans
7. Privacy and data protection in the field of research
8. Research involving animals
9. Biobanking for research purposes
10. Embryo and stem cell research
11. Genetic testing
12. Issues related to environmental impact assessment

Due to the significant role of legislation on risk assessment and evaluation, as well as the concept of precaution in guiding research and innovation, and assessing their impact, part two offers a more detailed overview of risk analysis approaches in EU legislation and briefly investigates how research and innovation are taken into account in EU policies. Part two also gives insights on the relationship and possible impact of risk-based regulation on Research and Innovation, while taking into account the different type of assessments address by policies related to risk analysis and in particular the role of the Precautionary Principle. In this text, risk analysis refers to risks related to environmental, health and safety issues (EHS) and concerns on ethical, legal and societal aspects (ELSA). Other risks relevant for policy action, such as business and financial risks, are not taken into consideration. It is structured in three main parts:

- Concept, procedures, structures, areas of application of risk analysis and the references to the precautionary principle in EU primary and secondary legislation;[1]
- Policies for research and innovation in EU: definition and approaches, relevant sectors, priorities regarding risks and ethical and societal concerns.
- Cases studies on selected research and innovation areas, relevant both in terms of risk analysis and economical impact at EU level

[1] Secondary sources are legal instruments based on the Treaties and include unilateral secondary law (e.g. regulations, directives, decisions, opinions and recommendations;) and conventions and agreements.

3 INTRODUCTION

3.1 CONTEXT

Recital 29 of the regulation on Horizon 2020[2] states that "Research and innovation activities supported by Horizon 2020 should respect fundamental ethical principles. The opinions of the European Group in Ethics in Science and New Technologies should be taken into account." Moreover in research activities issues of animal welfare and public health should be taken into account.

Ethics review and appraisal constitutes an integral part of the research proposal evaluation process by the European Commission (EC). All projects submitted to the EC are evaluated from the point of view of the ethical and social impact. The evaluation has two stages: ethics screening and a more in-depth ethics review in the case of some projects. Moreover, in some cases there is a need of an ethics follow-up and audit. The ethical issues are listed in the "Ethics Issues Table template"[3]. It includes questions on the use of human embryos/fetuses, participation of humans, use of human cells/tissues, personal data, animals, involvement of non-EU countries, as well as questions on environment, health and safety, dual use, misuse. Those submitting a proposal are required to perform an ethics self-assessment.

Article 19 of the regulation on Horizon 2020 lays down the ethical principles applicable to all research funded by the programme. According to this provision:

1. All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.

   Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.

2. Research and innovation activities carried out under Horizon 2020 shall have an exclusive focus on civil applications.

3. The following fields of research shall not be financed:
   (a) research activity aiming at human cloning for reproductive purposes,
   (b) research activity intended to modify the genetic heritage of human beings which could make such changes heritable, but research relating to cancer treatment of the gonads can be financed.
   (c) research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

[2] European Parliament and the Council, Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC, 11.12.2013.
http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf
[3] European Commission, The EU Framework Programme for Research and Innovation, Version 1.1, 11.07.2014.
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/ethics-eit_en.pdf

4. Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden.

There is potential to revise the fields of research set out in paragraph 3 that are currently explicitly excluded from community funding.

In addition to setting legal rules, the EC has produced a number of guidance documents on the ethical aspects of research and ethics evaluation of research proposals. Some of them are of a general nature, for example *"A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research."*[4] Others are domain-specific and include guidance notes on: social sciences and humanities, ethics and food related research, research on human embryos/foetus, clinical trials on medical products conducted with paediatric population, privacy, informed consent, animals, research in developing countries, dual use, ethnography/anthropology, as well as misuse/malevolent use.[5]

At the same time, at the level of individual states there are no mechanisms of ethics review as comprehensive as those established by the European Commission. Guidelines on how to conduct research can be found in different instruments. The main purpose of this deliverable is to identify and map those rules contained in laws and soft-law documents against the background of the EU legal and regulatory frameworks.

3.2 OBJECTIVES

The aim of this deliverable is to identify the legal frameworks that currently guide and/or constrain ethical procedures within research and research assessment in the EU. The partners paid attention to both regulatory frameworks and soft-law instruments, including those developed at international level, which establish declaratory principles addressed to national authorities and research communities. Furthermore, in addition to existing regulation, the partners studied ongoing developments with reference in particular to emerging issues in bioethics and in the regulation of emerging technological applications such as nanoparticles and other nanosubstances in consumer products.

The partners examined the legal and regulatory frameworks at the EU level as well as eight selected Member States, taking into account the international legal environment. The eight selected Member States are the same as those selected in WP1, Task 1.5 for the international comparison of ethics assessment practices: The Netherlands, United Kingdom, Spain, Austria, Poland, Serbia, France and Germany. Other member states were also surveyed to get a more complete overview.

[4] European Commission, A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research, 2012.
http://ec.europa.eu/research/participants/data/ref/fp7/89797/improper-use_en.pdf

[5] For more information: http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

3.3 METHODOLOGY

In order to prepare this deliverable a three-step approach was adopted. First detailed questionnaire for country studies was designed to gain a general overview of existing regulations (Annex 1).

Eight national reports were then prepared, incorporating the results of the questionnaire. In addition partners prepared studies on EU level regulations in selected fields that corresponded to those identified in the original questionnaire.

Finally, in the third stage, the results of the reports were synthesized into the present deliverable to give first an overview on the EU level of the fields identified plus a comparative analysis between the national approaches between the selected countries.

4 SCIENTIFIC FREEDOM AND FREEDOM OF RESEARCH IN EU LAW AND REGULATORY FRAMEWORK

4.1 EU LEVEL

In the EU, legal guidelines on how to conduct research can be found in legal acts at different levels: from the Charter of Fundamental Rights[6] and the EU Treaties to specific acts of secondary law such as directives and regulations.
The Charter of Fundamental Rights of the European Union does not contain a separate article devoted solely to the freedom of science or research. These provisions are laid down together with guarantees of the freedom of arts and followed by the rule on academic freedom, i.e. according to Article 13 *"The arts and scientific research shall be free of constraint. Academic freedom shall be respected."*[7]

According to the official explanations relating to the Charter, *"The right [freedom of the arts and sciences] is deduced primarily from the right to freedom of thought and expression. It is to be exercised having regard to Article 1 and may be subject to the limitations authorised by Article 10 of the ECHR."*[8]. The explanations, in order to shed some light on the normative content of Article 13, refer to Article 1 of the Charter that speaks of human dignity stating "*[h]uman dignity is inviolable. It must be respected and protected."*[9]They also refer to Article 10 of the European Convention on Human Rights.[10] Which provides the right to freedom of expression but does not explicitly mention science or research.

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[6] European Convention, Charter of Fundamental Rights of the European Union (2000/C 364/01), the Official Journal of the European Communities, 02.10.2000.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT
[7] Ibid.
[8] Praesidium of the Convention, Explanations Relating to the Charter of Fundamental Rights (2007/C 303/02), 14.12.2007
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2007:303:0017:0035:en:PDF
[9] The European Convention, the Charter of Fundamental Rights of the European Union (2000/C 364/01), the Official Journal of the European Communities, 02.10.2000.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT
[10] The Council of Europe, Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocols Nos. 11 and 14, supplemented by Protocols Nos. 1, 4, 6, 7, 12 and 13, Rome, 04.11.1950.
http://www.echr.coe.int/Documents/Convention_ENG.pdf

4.2 OTHER RELEVANT PROVISIONS OF THE CHARTER: PROTECTION OF THE PERSON AND THE ENVIRONMENT, SOLIDARITY BETWEEN GENERATIONS, SUSTAINABLE DEVELOPMENT.

Guidelines on the way research should be conducted, as well as on its goals, can also be found in other provisions of the Charter. The Preamble states "*[The Union] seeks to promote balanced and sustainable development (...)*"[11]
Other provisions of importance include:

- Article 3 "**Right to the integrity of the person**": *"2. In the fields of medicine and biology, the following must be respected in particular:*
  (a) the free and informed consent of the person concerned, according to the procedures laid down by law;
  (b) the prohibition of eugenic practices, in particular those aiming at the selection of persons;
  (c) the prohibition on making the human body and its parts as such as source of financial gain;
  (d) the prohibition of the reproductive cloning of human beings."[12]

  The explanation on Article 3 refers to the judgment of the Court of Justice in *Case C-377/98 Netherlands v European Parliament and Council*[13] concerning the issue of legal protection of biotechnological inventions. The Court confirmed that a fundamental right to human integrity is part of Union law and encompasses, in the context of medicine and biology, the free and informed consent of the donor and recipient.
  Moreover, the explanation emphasises that the principles of Article 3 are already included in the Convention on Human Rights and Biomedicine[14] adopted by the Council of Europe. The text of the explanation goes on to clarify that the Charter does not set out to depart from those principles and therefore prohibits only reproductive cloning. It neither authorizes nor prohibits other forms of cloning. It does not, however, prevent the legislature from prohibiting them.
  Finally the reference to eugenic practices, in particular those aiming at the selection of persons, relates to the possible situations in which selection programmes are organized and implemented, involving campaigns for sterilization, forced pregnancy, compulsory ethnic marriage among others, all of which are acts deemed to be international crimes in the Statute of the International Criminal Court[15] adopted in Rome on 17 July 1998.
- Article 8 "**Protection of personal data"**: "*1. Everyone has the right to the protection of personal data concerning him or her. 2. Such data must be processed fairly for specific purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by the law. Everyone has the right of access to data*

[11] European Convention, Charter of Fundamental Rights of the European Union (2000/C 364/01), the Official Journal of the European Communities 02.10.2000.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT
[12] Ibid.
[13] The Court of Justice, Judgement C-377/98 Kingdom of the Netherlands v European Parliament and Council of the European Union of 9 October 2001.
http://curia.europa.eu/juris/showPdf.jsf;jsessionid=9ea7d2dc30dd0c13c2ed315349cba931a271a91f5efa.e34KaxiLc3qMb40Rch0SaxuPahb0?text=&docid=46255&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=310941
[14] Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 04.04.1997.
http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm
[15] The United Nations General Assembly, Rome Statute of the International Criminal Court (A/CONF.183/9), Rome, 07.07.1998.
http://www.icc-cpi.int/nr/rdonlyres/ea9aeff7-5752-4f84-be94-0a655eb30e16/0/rome_statute_english.pdf

which has been collected concerning him or her, and the right to have it rectified. 3. Compliance with these rules shall be subject to control by an independent authority."[16]

The conditions and limitations for the exercise of the right to the protection of personal data are contained in the Directive 95/46/EC[17] on the protection of individuals with regard to the processing of personal data and on the free movement of such data[18] and the Regulation No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.[19]

- Article 35 "**Health care"**: *"Everyone has the right of access to preventive health care the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities*."[20]
  This article is based on Article 168 of the Treaty on the Functioning of the European Union[21], and Articles 11 and 13 of the European Social Charter. The Treaty by means of Article 168 obliges the Union to promote research into the causes, transmission and prevention of major health dangers.
- Article 37 "**Environmental protection"**: *"A high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development."*[22]

  Article 37 of the Charter has been based on Articles 3(3) of the Treaty on European Union (TEU)[23] and Articles 11 and 191 of the Treaty on the Functioning of the EU (TEFU). It also draws on the provisions of some national constitutions.

  According to Article 3 of TEU, the Union shall work for the sustainable development of Europe aiming at, among others, a high level of protection and improvement of the quality of the environment. It shall promote scientific and technological advance. Moreover the Union shall promote "solidarity between generations".

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[16] European Convention, Charter of Fundamental Rights of the European Union (2000/C 364/01), the Official Journal of the European Communities, 02.10.2000.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT

[17] There are ongoing works to replace the directive with the new General Data Protection Regulation.

[18] The European Parliament and the Council, Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:31995L0046

[19] European Parliament and the Council, Regulation (EC) No 45/2001 of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32001R0045

[20] European Convention, Charter of Fundamental Rights of the European Union (2000/C 364/01), the Official Journal of the European Communities, 02.10.2000.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXThttp://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT

[21] European Union, Treaty on the Functioning of the European Union, 25.03.1957.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT

[22] European Convention, Charter of Fundamental Rights of the European Union (2000/C 364/01), the Official Journal of the European Communities, 02.10.2000.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT

[23]The European Union member states, consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (2012/C 326/01), Official Journal C 326, 26.10.2012.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012M/TXT

According to Article 11 of TFEU *"Environmental protection requirements must be integrated into the definition and implementation of the Union's policies and activities, in particular with a view to promoting sustainable development."*[24]

According to Article 191 *"Union policy on the environment shall contribute to pursuit of the following objectives: preserving, protecting and improving the quality of the environment; protecting human health; prudent and rational utilisation of natural resources; promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change."*[25] According to that provision Union policy on the environment should be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

In preparing its policy on the environment, the Union takes account of available scientific and technical data, environmental conditions in the various regions of the Union, the potential benefits and costs of action or lack of action, the economic and social development of the Union as a whole and the balanced development of its regions.

- In addition, these are simply a baseline, as noted in Article 53 "Level of protection": *"the Charter offers the minimum level of protection and Member States may introduce stronger measures."*

4.3 NATIONAL LEVEL

Scientific freedom is not explicitly covered by constitutions in all EU member states, though some states consider "scientific freedom" to be a "freedom of speech" issue, and therefore subject to free speech protections.

In **Austria** freedom of research is guaranteed by Article 17 of the Basic Law on the General Rights of Nationals (Staatsgrundgesetz), which declares science and its teachings as "free".[26] In **Germany** scientific freedom is protected under article 5 of the Basic Law (Grundgesetz). According to Article 5.3 sentence 1: "Arts and sciences, research and teaching shall be free."

France's Code of Research (Code de la Recherche) stipulates that, in public research, the status of research staff or the rules governing their employment must guarantee the autonomy of their science.[27]

According to the **Polish** Constitution "[t]he freedom of artistic creation and scientific research as well as dissemination of the fruits thereof, the freedom to teach and to enjoy the products of culture, shall be ensured to everyone" (Article 73). In **Serbia,** freedom of scientific and

[24] The European Union member states, Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (2012/C 326/01), Official Journal C 326, 26.10.2012. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT

[25] Ibid.

[26] Article 17 Staatsgrundgesetz: „Die Wissenschaft und ihre Lehre ist frei." („Science and its teachings are free".), Germany, 21.12.1867.

[27] Article L411-3 of the Code de la Recherche, France, 16.01.2015.

artistic creativity is guaranteed by Article 73 of the Constitution: "[a]uthors of scientific and artistic works shall be guaranteed moral and material rights in accordance with the law. The Republic of Serbia shall assist and promote development of science, culture and art". The **Spanish** Constitution recognises, in Article 20, the right to: **"**a) Express and spread freely thoughts, ideas and opinions through words, writings or any other means of reproduction; b) To the literary, artistic, scientific and technical production and creation; c) To the freedom of teaching; d) To communicate or receive freely truthful information by any means. The law will establish the right to the conscience clause and the professional secret in the exercise of these liberties."

While the **United Kingdom** does not have a unified written constitution, relevant protections are found at a statutory level in the Education Reform Act of 1988, which guarantees academic freedom for academic staff. Hardly any case law exists specifically regarding "scientific freedom,", howeverrecent controversy has emerged over the use of the Freedom of Information Act, which obliges public institutions to allow public access to scientific data which has been produced by publicly funded means. The status of scientific research and the freedom to engage is long revered within the United Kingdom, which boasts of having the oldest known learned society still in existence concerning science, that is, the Royal Society. Notably, the Human Rights Act of 1998 entitles individuals the right to freedom of expression, as found in the European Convention.

The Constitution of **the Netherlands** does not specifically address the issue of scientific freedom. There is no doubt, however, that it is guaranteed by the provisions on freedom of expression in Article 7 of the Constitution, according to which "1. No one shall require prior permission to publish thoughts or opinions through the press, without prejudice to the responsibility of every person under the law (…) 3. No one shall be required to submit thoughts or opinions for prior approval in order to disseminate them by means other than those mentioned in the preceding paragraphs, without prejudice to the responsibility of every person under the law (…)."

There is wide consensus that scientific freedom may be limited in order to protect other basic rights and freedoms (e.g. the prohibition of inhuman or degrading treatment or the right to privacy), as long as the limitation is proportionate and properly justified. Moreover, the law in the Netherlands allows for certain types of research to be conducted only following the granting of permission by an ethical committee (this is typically the case with regard to medical research where specific rules apply to clinical trials, as well as the experiments on animals). In those cases, carrying out research without permission shall entail sanctions. As regards the exact meaning and the limits of scientific freedom, guidance is often offered by the jurisprudence of highest national courts and tribunals**.** For example, in one of the most recent rulings that concerned amendments to the Act on the Regulation of Genetic Engineering[28] (Gesetz zur Regelung der Gentechnik, Gentechnikgesetz, Gentechnikgesetz – Genetic Engineering Act - GenTG) the Federal Constitutional Court of Germany recalled the most important aspects of constitutional guarantees concerning freedom of scholarship.

According to the Court:

- "like other unconditionally guaranteed fundamental rights the freedom of scholarship may be restricted on the basis of conflicting constitutional law (…), in general there must be a statutory basis for this";

[28] Federal Constitutional Court of Germany (Bundesverfassungsgericht), 1 BvF 2/05, 24.11.2010.

- "a conflict between constitutionally protected fundamental rights must be solved by recourse to further relevant constitutional provisions and principles and to the principle of practical concordance by interpretation of the constitution";
- "the protection of human life and health, of the occupational freedom and freedom of property of those potentially affected and of natural resources (Article 2.2 sentence 1, Article 12.1, Article 14.1, Article 20a GG) are important values of constitutional status that justify a restriction of the freedom of scholarship";
- "in the weighing of the opposing interest, it must be taken into account in favor of the freedom of scholarship that precisely a scholarship freed from considerations of utility for society and political expedience ultimately serves the state and society best";

In the case law of highest national courts and tribunals, the issue of scientific freedom is raised in different contexts, such as, for example: financial claims of academic staff, access to public information, or the protection of privacy (Poland), relation to the freedom of expression (Spain), or the obligation of employees towards employers (Austria).

Apart from guarantees of scientific freedom, other Constitutional provisions that set conditions for or explicitly ban certain types of research should be borne in mind when conceptualizing the limits of this freedom. In Serbia, for example the Constitution stipulates in Article 24 that cloning of human beings is prohibited, and in Article 25 that nobody may be subjected to medical and other experiments without their free consent.[29] Similarly, in Poland the Constitution prohibits conducting experiments without consent and states in Article 29 that "[n]o one shall be subjected to scientific experimentation, including medical experimentation, without his voluntary consent."

5 THE RIGHT TO ENJOY THE BENEFITS OF SCIENTIFIC PROGRESS AND ITS APPLICATIONS

5.1 EU

The right to enjoy the benefits of science, enshrined in various international and regional instruments,[30] is not explicitly mentioned in the Charter of Fundamental Rights. The concept itself has been largely underdeveloped, though greater debate and attention has been given in the recent years. International documents, such as Articles 27 of the Universal Declaration of Human Rights, Article 15 of the Universal Declaration on Bioethics and Human Rights, and Article 15 of the International Covenant on Economic, Social and Cultural rights have given shape to the debate. However, what constitutes "benefits" continues to be a point of contention. Historically, the notion of "benefits" has tended to focus on cultural participation in the progress of science, whether through support for research programs or establishing means of disseminating and sharing the outcomes of scientific research. While the Charter on Fundamental Rights does not refer to the benefits of scientific progress, the Convention on Human Rights and Biomedicine does make mention in Article 2 that "The interests and welfare of the human being shall prevail over the sole interest of society or science." Current efforts to address the right to enjoy the benefits of scientific progress and its applications

[29] The National Assembly of the Republic of Serbia, Constitution of the Republic of Serbia (Ustav Republike Srbije), Official Gazette of the Republic of Serbia no. 98/2006, Serbia, 30.09.2006. www.srbija.gov.rs/cinjenice_o_srbiji/ustav.php?change_lang=en

[30] Article 13 of the American Declaration of the Rights and Duties of Man, the Ninth International Conference of American States, 04.1948, Article 27 of the Universal Declaration of Human Rights, the General Assembly of the United Nations, 10.12.1948, Article 15 of the International Covenant on Economic, Social and Cultural Rights, Resolution 2200A (XXI) of the General Assembly of the United Nations, 16.12.1966– binding norm.

often involve reference to the World Trade Organization's TRIPS agreement, intellectual property rights, and what has been referred to as "benefit sharing." Recent participation by European actors, including representatives of the EU, to address the right to enjoy the benefits of scientific progress and its applications include the "Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications" in 2009. However, there are no EU level organizations dedicated specifically to the promotion of the right to enjoy the benefits of scientific progress and its applications. In light of these, there are also varying degrees of commitment to this right, as evidenced below.

5.2 NATIONAL LEVEL

National legislation or official documents hardly ever refer to the right to enjoy the benefits of scientific progress and its application. This proves that the right, proclaimed at international level, remains highly underdeveloped.[31] Information as to the steps that states should take in order to fulfill their commitments to upholding acts of international law (Article 27 of the Universal Declaration of Human Rights and Article 15 of the International Covenant on Economic, Social and Cultural Rights) can be found in the country reports submitted to the Committee on Economic, Social and Cultural Rights under Articles 16 and 17 of the International Covenant on Economic, Social and Cultural Rights.[32] However most activates referred to by the respective governments, even if they are included in the section entitled as such, are only loosely linked to the right to enjoy the benefits of scientific progress and its application.

The fourth periodic report submitted by **Austria** under articles 16 and 17 of the Covenant lists the following topics with regard to enjoying the benefits of scientific progress: [33]

- Integration through sport and equal opportunities in society,
- Access to the cultural heritage of mankind,
- Participation in cultural life by children,
- Participation of ethnic groups in Austria in cultural life,
- Education in the field of culture and the arts in schools and in vocational education,
- Access to the benefits of scientific progress (e-government strategy).

The e-government strategy and the focus on access to the internet seem to be those points which are closest related to the right to enjoy the benefits of scientific progress.

The latest report from **Germany** submitted to the Committee on Economic, Social and Cultural Right was published in 2010. It is the fifth periodic report, and covers the period between years 2006 and 2008. The report does not refer to the right to enjoy the benefits of scientific progress, nor do the previous periodic reports.

While **France's** two most recent reports (2014, 2007) do not refer to the right to enjoy the benefits of scientific progress explicitly, the first two reports of 2000 and 1984 emphasize France's belief in its commitment to the right to enjoy the benefits of scientific progress

[31] Y. Donderas, The right to enjoy the benefits of scientific progress: in search of state obligations in relation to health, Med Health Care Philos. Nov 2011; 14(4): 371–381, available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3190088/

[32] These can be found at Office of the High Commissioner for Human Rights site: http://tbinternet.ohchr.org/_layouts/treatybodyexternal/TBSearch.aspx?Lang=en&TreatyID=9&DocTypeID=29

[33] UN Committee on Economic, Social and Cultural Rights (CESCR), Implementation of the International Covenant on Economic, Social and Cultural Rights : 4th periodic reports submitted by States parties under articles 16 and 17 of the Covenant: Austria, E/C.12/AUT/4, 29.10.2012. http://www.refworld.org/publisher,CESCR,STATEPARTIESREP,AUT,521db91a4,0.html

through its public funding of scientific research, support of industrial research, and activities to promote the dissemination of scientific data.

In the most recent report that has yet to be officially submitted to the Committee,[34], the **Polish** government sets out the recent reforms of different laws governing science in Poland. Among the goals of the reform include the need to establish a stricter link between science and industry. The government stresses that the national programme on research (*Krajowy program badań*) allows for the appropriation of funds to those scientific fields and disciplines that have the greatest influence on social and economic development.[35] The state budget finances activities aimed at promoting science. Moreover, according to the government, the right to benefit from scientific advances is implemented by means of ministerial programs that have as their objective the support of internationalization of journals published by universities that do not receive subsidies for statutory activities, as well as scientific libraries that are not part of research entities. There is a dedicated program to support the development of the humanities. The government also points out, that in 2010, an Ethics in Science Commission at Polish Academy of Sciences was created. It acts, in cases of scientific misconduct, among other issues. Moreover, at the a Panel on Good Academic Practices has been set up at the Ministry of Science.

The latest report from **Serbia** submitted to the Committee on Economic, Social and Cultural Right was published in 2013.[36] It was the second periodic report under the International Covenant on Economic, Social and Cultural Rights. In the part that refers to Article 15, the report did not mention any steps taken to safeguard the right to enjoy the benefits of scientific progress and its applications. Moreover, science in general was hardly mentioned under this article.

The Spanish government submitted the latest report to the Committee on Economic, Social and Cultural Right was published in 2003. The report does not explicitly mention the right to enjoy the benefits of science; it mainly refers to the obligation of the authorities to make culture accessible to all citizens.

The **United Kingdom's** 2001 report heavily emphasizes the right to enjoy the benefits of scientific progress and its applications, going so far as to state, "The well-developed intellectual property system, by providing protection for a limited time, encourages the publication of new technological developments, promotes understanding and stimulates further research. Otherwise the only restrictions to access to, or use of, scientific progress are those necessary to protect the public from developments which are either unsafe or generally accepted to be unethical.." It also highlights: Public enjoyment and promoting understanding, promoting women in science, engineering and technology, science festivals, science centres, science museums, promotion of scientific research, The Foresight Programme, The Scientific Budget and university research funding, Technology transfer, Monitoring of use of science and technology and protection of the public, Protection of the environment and promotion of

[34] It can be accessed on the website of the Polish Ministry of Labour and Social Policy.
http://www.mpips.gov.pl/spoleczne-prawa-czlowieka/organizacja-narodow-zjednoczonych-miedzynarodowy-pakt-praw-gospodarczych-spolecznych-i-kulturalnych/sprawozdania-polski-z-wykonania-miedzynarodowego-paktu-praw-gospodarczych-spolecznych-i-kulturalnych/vi-sprawozdanie-polski-za-lata-2007-2013/

[35] This includes: new technologies in the field of energy, civilization diseases, new drugs and regenerative medicine; advanced information technologies, telecommunication and mechatronics; modern materials technology; the environment, agriculture and forestry; social and economic development of Poland in view of increasingly global markets, security and defense of the state.

[36] Office of the High Commissioner for Human Rights.
http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=E%2fC.12%2fSRB%2f2&Lang=en

sustainable development, International collaboration, Bilateral cooperation staff, and Weapons and toxic substances.

The Netherlands' combined fourth and fifth report was published in 2009 (United Nations Economic and Social Council 2009). The 2009 report was the last report to the United Nations Economic and Social Council. In the section devoted to the right to enjoy the benefits of scientific progress, the reports provides information on the protection of scientific authors' moral and practical interests, as well as the implementation of the relevant EU directives.

6 SCIENTIFIC INTEGRITY: CODES OF CONDUCT AND SANCTIONS FOR SCIENTIFIC MISCONDUCT

6.1 EU

The Charter of Fundamental rights does not explicitly refer to scientific integrity. However, there is a mix of historical, soft-law, and statutory acts which guide scientific integrity within the European Union. While no single legal framework exists, the historical basis for the creation of protocols and protections is often invoked through the citation of documents such as the:

- *Nuremberg Code*
- *Declaration of Helsinki* (World Medical Association)
- *Convention on Human Rights and Biomedicine* (EU)
- *Additional Protocol Concerning Biomedical Research* (EU)
- *Universal Declaration on Bioethics and Human Rights* (UNESCO)
- *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS)

In 2012, the European Research Council (ERC), the public body for funding scientific and technological research within the EU, established the Standing Committee on Conflict of Interests, Scientific Misconduct and Ethical Issues (CoIME) with the responsibility for "formulating guidelines on conflict of interest, fraud and ethical matters related to any facet of the ERC's competences, clarifying criteria and considering any particular instance or situation where ethical concerns may arise.[37]" However, the ERC's Scientific Misconduct Strategy, still recognizes the primary responsibility of host institutions applying for ERC funding to oversee potential detection, investigation, and adjudication for scientific misconduct. The strategy outlines its procedure as follows:

> "The ERCEA Director will, in consultation with CoIME, perform an initial assessment. Where this assessment suggests that the allegations received deal with issues that might involve an actual case of scientific misconduct, the Director shall proceed with a more detailed assessment in close collaboration with COIME
>
> The CoIME, in close collaboration with the ERCEA Director, will consider whether it is within its remit and competence to assess the scientific and ethical aspects of the case, whether the evidence is sufficient or whether additional review of the information is needed in order to decide whether a breach of research integrity did occur. If necessary, the CoIME may consult other members of the ERC Scientific Council and ERCEA staff and/or nominate external experts for appointment by the

[37] The Standing Committee on Conflict of Interests, Scientific Misconduct and Ethical Issues (CoIME). http://erc.europa.eu/about-erc/organisation-and-working-groups/standing-committees/Conflict-of-Interests-Scientific-Misconduct-and-Ethical-Issues

ERCEA Director who would act as advisors to the ERC in dealing with specific cases of scientific misconduct.

Having reached a conclusion (with or without the help of external experts), the CoIME will inform the ERCEA Director in writing about its opinion and will offer recommendations on how to handle the case. In the event of CoIME concluding that the case is potentially serious but cannot reach a consensus on how to deal with it the matter will be brought to the attention of Scientific Council who will offer an opinion on how to proceed without delay.

Having received these conclusions the ERCEA Director will make the final decision according to his/her own discretion or judgment."

Other attempts to address scientific misconduct on a European level exist in the European Science Foundation's "*European Code of Conduct for Research Integrity."*Alongside ALLEA, All European Academies, ESF's code draws on the historical bases and provides a Code of Conduct, Guidelines for Good Practice Rules, along with Recommended Principles for Investigating Scientific Misconduct. Another notable international organization in this area is the OECD Global Science Forum Practical Guide for the Investigation of Research Misconduct Allegations in International Collaborative Research Projects. These documents lack any legal authority, though they are widely cited within national and institutional frameworks for addressing scientific integrity and misconduct.

6.2 NATIONAL LEVEL

This section discusses in some detail the most significant national actors and frameworks in the field of scientific integrity. Codes of conduct for scientific integrity are usually soft-law documents established by research integrity agencies, science-funding organizations, or by universities. Professional groups have their own codes of conduct partly devoted to research activities. Principles of scientific integrity are rarely laid down in legally binding acts.

In **Austria,** the major player in this area is the Austrian Agency for Research Integrity (OeAWI). The Agency was established in December 2008 as an association in accordance with the Austrian Associations Act and founded by 12 Austrian universities as well as the Austrian Academy of Sciences, the Vienna Science and Technology Fund (WWTF), IST Austria and the Austrian Science Fund (FWF). The agency is responsible for investigating alleged cases of scientific misconduct in Austria by an independent body consisting of distinguished non-Austrian scholars. The Agency for Research Integrity has neither an arbitrary nor an adjudicative function but offers a neutral and factual platform for investigating thoroughly and impartially (alleged) cases of scientific misconduct. Any individual or institution in Austria can approach the Commission of Research Integrity which is free to decide whether an allegation is to be pursued. As the Agency is not based on the University Act, but is organized as an association, it does not have any prosecuting powers. Legal consequences of misconduct are to be prosecuted by the Universities individually.[38] Furthermore, the agency aims to prevent research misconduct and to raise awareness, offering lectures and workshops on "good scientific practice" to its member institutions. The Agency

[38] See also Austrian Agency for Research Integrity site (Agentur für wissenschaftliche Integrität): http://www.oeawi.at/en/index.html

published Rules of procedure for the investigation of alleged scientific misconduct[39] as well as Guidelines for the investigation of alleged scientific misconduct.[40] In addition, each university issued individual guidelines on good scientific practice.[41] Content-wise, the guidelines are quite different depending on which field of research is concerned. In the medical field, the guidelines cover ethical issues based on the Helsinki Declaration. In other fields, they mainly relate to scientific integrity, authorship, cooperation, documentation, and misconduct. Possible sanctions depend on the legal quality of those guidelines. The respective opinion of the Austrian Bioethics Committee summarizes the legal sanctions as follows:

> "At some universities, these guidelines form part of the statutes and therefore qualify as legal ordinances; while at others they are drawn up by the rector and can thus be understood as instructions. At yet other universities, rules of good scientific practice are established by the senate and do not form part of the statutes; here, they are neither ordinances, due to the lack of competence of the senate, nor are they instructions specified by staff regulations, being only recommendatory in nature. Furthermore, the legal status of the guidelines that are issued and published by the rector (which, in fact, could be termed instructions) are unclear, but at the same time, however, expressly obligate the scientific staff to accept these guidelines in writing. This implies that these guidelines should only become binding once they have been accepted in individual cases. The question of how these – actually non-binding – guidelines can obligate the staff to accept them remains, however, an unanswered question."

As far as the most important soft law regulations in **Germany** are concerned, the German Research Foundation (DFG) established 16 recommendations regarding basic rules of good

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[39] Commission for Research Integrity: Rules of procedure for the investigation of alleged scientific misconduct. http://www.oeawi.at/downloads/Rules%20of%20procedure_Sept_2014.pdf

[40] Annex I to the Rules of Procedure of the Commission for Research Integrity: Guidelines for the investigation of alleged scientific misconduct. http://www.oeawi.at/downloads/Richtlinien_zur_Untersuchung_von_Vorwuerfen_wissenschaftlichen_Fehlverhaltens_e.pdf

[41] Guidelines of good scientific practice: Medical University of Vienna: http://www.meduniwien.ac.at/files/7/8/goodscientificpractice.pdf, Medical University of Graz: https://www.medunigraz.at/images/content/file/forschung/gsp/GSP_Standards.pdf, Medical University of Innsbruck: https://www.i-med.ac.at/mitteilungsblatt/2004/27.pdf, University of Vienna: http://www.phd-structural-biology.at/content/file/SL_005_Regulations_relating_to_good_scientific_practice_infoblatt.pdf, University of Graz: http://www.uni-graz.at/zvwww/gesetze/satzung-ug02-04.html, University of Salzburg: http://www.uni-salzburg.at/fileadmin/multimedia/Molekulare%20Biologie/Qulit%C3%A4tssicherung/richtlinien_zur_sicherung_guter_wissenschaftlicher_praxis.pdf, University of Innsbruck: http://www.uibk.at/fakultaeten-servicestelle/handbuch-fuer-lehrende/#Richtlinien zur "Sicherung guter wissenschaftlicher Praxis", Donauuniversität Krems applies the rules of the European Charter for Researchers : https://www.i-med.ac.at/mitteilungsblatt/2004/27.pdf, Graz University of Technology: http://portal.tugraz.at/portal/page/portal/Files/Services/files/RL_GuteWissPraxis.pdf, University of Natural Resources and Applied Life Sciences: http://www.boku.ac.at/fileadmin/data/H05000/H13000/Ombudsstelle/Guidelines.pdf, Vienna University of Veterinary Medicine: http://www.vetmeduni.ac.at/uploads/media/GoodScientificPractice_01.pdf, Vienna University of Technology: http://www.tuwien.ac.at/dle/universitaetskanzlei/richtlinien_und_verordnungen/code_of_conduct_fuer_wissenschaftliches_arbeiten/

scientific practice in 1998.[42] According to the recommendations of the DFG, universities and research institutes should specify which behaviours would be regarded as scientific misconduct. Each institution has its own definition of scientific misconduct, as well the list of actions regarded as such, but nevertheless they are very similar to those of the DFG. Within DFG, the Committee of Inquiry on Allegations of Scientific Misconduct decides whether scientific misconduct has occurred. It investigates allegations of applicants, funding recipients, others responsible for the use of DFG funds, reviewers and members of DFG bodies involved in consultation and decision-making processes[43]. Besides the Committee, Research Ombudsman (former "Ombudsman of the DFG") is an independent committee, involved in all matters concerning good scientific practice and scientific misconduct. Unlike the Committee of Inquiry on Allegations of Scientific Misconduct, this institution can be contacted directly, regardless of any connections with DFG[44].

The DFG recommendations were implemented in many codes of conduct of professional societies such as the Max Planck Institute, German Chemical Society and German Rectors' Conference. On 26 October 2001, DFG established rules of procedure for dealing with scientific misconduct, which applies to applicants, grant recipients and anyone responsible for the use of DFG funds, as well as DFG reviewers and all members of DFG committees, who participate in decision-making or reviewing processes.

Each institution has its own procedures for dealing with scientific misconduct, but they are much alike. The judgment of the Federal Administrative Court of German (Budesverwaltungsgericht, BVerwG) of 11.12.1996 (BVerwG 6 C 5.95)[45] is noteworthy as it specifies the procedure for dealing with misconduct in higher education and research institutes. Pursuant to the judgment in question, in the event of scientific misconduct of any kind, a special committee should be called up to investigate all circumstances of the case, so that further actions can be decided on.

Since much of the research in **France** is carried out within the public sector, researchers can be subject to misconduct rules that apply to civil servants. Additionally, the major research organizations (CNRS, INSERM, INRA) have established statutory rules (institutional regulation) on scientific integrity. These guidelines incorporate other instruments which address scientific integrity principles, as seen with the INRAThe INRA Code of Conduct[46]is based on a set of laws, regulations or institutional guidelines which govern the professional activity of all staff. The central texts that make up the framework of the code, designed to promote the individual responsibility of each employee, include: French law n°83-634 amended 13 July 1983 on the rights and responsibilities of civil servants; the Code of research; the Code of education; the European charter for researchers (11 March 2005); and the Singapore statement on research integrity (2010)[47].

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[42] German Research Foundation (Deutsche Forschungsgemeinschaft), Proposals for Safeguarding Good Scientific Practice, Germany, 01.1998.
http://www.izw-berlin.de/tl_files/downloads/self_regulation_98.pdf

[43] For more information about the Committee of Inquiry on Allegations of Scientific Misconduct: http://www.dfg.de/en/dfg_profile/statutory_bodies/joint_committee/inquiry_misconduct/index.html

[44] For more information about the Research Ombudsman (Ombudsman of the DFG): http://www.dfg.de/en/research_funding/principles_dfg_funding/good_scientific_practice/ombudsman/index.html

[45] Federal Constitutional Court of Germany (Bundesverfassungsgericht), 6 C 5.95, 11.12.1996.

[46] The French National Institute For Agricultural Research.
http://institut.inra.fr/en/Missions/Promoting-ethics-and-a-code-of-conduct/Tous-les-dossiers/Code-of-conduct/Code-of-conduct

[47] Singapore Statement on Research Integrity.
http://www.singaporestatement.org/downloads/singpore%20statement_A4size.pdf

A report dated September 15, 2010[48] issued eight recommendations:

- Edition of a good practice guide
- Adoption of a Charter of Research Integrity
- Developing prevention and education
- Installing case processing procedures
- Launching the offensive against plagiarism
- Negotiating with publishers equitable sharing of the integrity of publications
- Creating a national authority
- Implementing these recommandations within a year at the initiative of the Ministry of Research

Among these recommendations, only one has been followed so far, the signature of a National code of ethics of research jobs (Charte nationale de déontologie des métiers de la recherche[49]) on January 29, 2015.
This code has been signed by the following institutions: CNRS, Inserm, Inra, Inria, IRD, Cirad, Institut Curie and the universities (represented by the Conference of university Presidents.
The 7 principles of the code are:

- Compliance with legislation and regulations
- Reliability of the research work
- Communication
- Responsibility in the collective work
- Impartiality and independence in the evaluation and expertise
- Collaborative work and plurality of offices
- training

Scientists can also be subject to sanctions due to non-declaration or false declaration of conflict to of interests in Law No. 2013-907 of 11 October 2013 on the transparency of public life Penal provisions; Article 26: In particular, a non-statement or false statement is punishable by three years imprisonment and a € 45,000 fine.

Scientific misconduct can be penalized by institutionally internal rules. For example, the Scientific Delegation to Integrity (Delegation to scientific integrity, DIS) of the National Institute for Health and Medical Research (the National Institute for Health and Medical Research or INSERM). The DIS receives confidential allegations of misconduct to be accompanied with evidence to prove the facts. The DIS acts as a mediator seeking a solution between the parties concerned. However, the Directorate-General has sole authority to decide on the action to be taken, such as sanctions or reparations.

[48] Directorate General for Research and Innovation, Ministry of Higher Education and Research of France, Renforcer l'intégrité de la recherche en France, 15.09.2010.
http://www.h2mw.eu/INTEGRITE_JPA_RAPPORT_V%20Stephan.pdf
[49] Ministry of Higher Education and Research of France, National Center for Scientific Research (Centre national de la recherche scientifique), National code of ethics of research jobs (Charte nationale de déontologie des métiers de la recherché), France, 29.01.2015.
http://www.cnrs.fr/comets/spip.php?article119

In **Poland,** there are a number of documents established by different bodies over the years that touch upon the issue of scientific integrity.[50] Currently, cases of unethical behavior by academic staff can be, in the course of disciplinary proceedings, dealt with by a special commission established at the Polish Academy of Sciences – i.e. the Ethics in Science Commission at Polish Academy of Sciences. Moreover, the most serious instances of scientific misconduct, such as e.g. plagiarism are covered by the Act of 4 February 1994 on Intellectual Property Rights (Article 115) and, since they constitute a criminal offence, are dealt with by ordinary criminal courts.
The Ethics in Science Commission at Polish Academy of Sciences issues opinions in cases of alleged violations of rules of scientific integrity by employees of higher education institutions, particularly in proceedings dealt with by disciplinary commissions established at the universities. These opinions are binding. On its own initiative, the Commission may refer cases to the disciplinary commissions with the recommendation of initiating explanatory proceedings. The disciplinary body should inform the Commission about the results of the proceedings. The Commission authored the Ethical Code of a Researcher[51] that refers to The European Code of Conduct for Research Integrity of the European Science Foundation and All European Academies. The Code lists ethical principles and best practices, as well as ways of dealing with cases of scientific misconduct. In addition to the issuing of opinions on individual cases and preparation of the Code, the Commission is also tasked with disseminating standards of scientific integrity.

In **Serbia,** principles of scientific integrity are laid down in the Law on Scientific Research Activities[52]. In the same act it is declared that scientific work shall be free and not subjected to any limitations, except for those arising from observing of scientific standards and ethical principles in scientific research work, protection of human rights, and environmental protection.

Two scientific institutes – the Institute for Oncology and Radiology of Serbia (in January 2001) and the Institute for Medical Research at the Faculty of Medicine at the University of Belgrade (in February 2001) - were the first to adopt the Code of Ethics of Scientific Research – Good Scientific Practice.[53] The Faculty of Medicine adopted it in 2004. This document was established with the aim of providing high ethical standards for research, because high standards are dependent on quality scientific practice. In that sense:

- research should be conducted according to the latest scientific achievements,
- the applied methodology and results should be presented in a manner that ensures accuracy and verifiability,
- critical attitude and exactness should be applied to all stages of scientific research process,
- the results of scientific research should be published.

[50] Committee of Ethics in Science (CES), Good Manners in Science a set of Principles and Guidelines („Dobre obyczaje w nauce. Zbiór zasad i wytycznych"), Poland, 2001.
http://www.ken.pan.pl/images/stories/pliki/pdf/down.pdf
[51] Ethics in Science Commission at Polish Academy of Sciences (Komisja ds. Etyki w Nauce), The Ethical Code of a Researcher (Kodeks etyki pracownika naukowego), Poland, 2012.
www.instytucja.pan.pl/images/stories/pliki/Komisja_ds_Etyki_Nauce/dokumenty/Kodeks_etyki_pracownika_naukowego_31.12._2012.pdf
[52] The Parliament of the Republic of Serbia, Law on Scientific Research Activities (Zakon o naučno-istraživačkoj delatnosti), Official Gazette of the Republic of Serbia no. 110/2005 and 50/2006 –corr. and 18/2010, 24.03.2010.
www.paragraf.rs/propisi/zakon_o_naucnoistrazivackoj_delatnosti.html
[53] School of Medicine in Belgrade, the Code of Ethics of Scientific Research – Good Scientific Practice (Etički kodeks naučnoistraživačkog rada Dobra naučna praksa), Serbia, 03.2004.
http://www.doiserbia.nb.rs/img/doi/0039-1743/2007/0039-17430702132V.pdf

This Code of Ethics gives recommendations regarding the following: setting up research groups, tasks and care for young scientists, quality assurance in the laboratory, documentation and data storing and safeguarding, authorship and original nature of scientific publications and intellectual property. The code also involves the institution of ombudsman for scientific research activities - the ombudsman an is independent, competent individual, entitled by the scientific board of the institution. The Ombudsman is authorized to initiate preliminary procedure to investigate if there was a violation of good scientific practice.

In the **United Kingdom**, government funding for scientific research is provided by its seven Research Councils, which are overseen by the Research Council UK (RCUK). Each of the individual councils maintains a code of conduct, as does the RCUK. In order to receive funding, researchers must comply with both codes.[54]

Resnik *et al* describe the relevant misconduct sections of the code of the Research Council, "The RCUK's code defines six areas of unacceptable research conduct (i.e., misconduct), including falsification, fabrication, plagiarism, misrepresentation, mismanagement or inadequate preservation of data and/or primary materials, and breach of duty of care, which includes failing to take due care to protect human or animal subjects or the environment from harm. Institutions that receive funding from one of the Research Councils are responsible for publishing standards of conduct and investigating unacceptable behavior." Despite of lacking investigatory legal power, the agreements between institutions and the council allow the RUCK to maintain of oversight of investigations into research misconduct.[55]

Any medical researcher registered with the General Medical Council is also required to follow the RUCK's code of conduct upon penalty of losing their registration and license to practice medicine.[56]

In addition to the RUCK, the UK Research Integrity Office (UKRIO) is an independent body and registered charity that provides expert advice and guidance about the conduct of research. UKRIO provides confidential consultation on cases of alleged misconduct and publishes guidance on good research practices, misconduct investigation, and scientific retractions and also sponsors education and training on research integrity and publishes a blog and a list of useful resources on its website.[57]

Further efforts to address research integrity were made in April 2012, when Universities, the Higher Education Funding Council for England, Research Councils UK, the Wellcome Trust, and several government departments adopted an agreement to promote research integrity in their respective work.

In **Spain,** research centers, either national or regional, have developed their own codes of good scientific practice, based mainly on the laws 14/2011 on Science, Technology and Innovation, 14/2007 on Biomedical Research and 15/1999 of Personal Data Protection, as well as other relevant legislation and international recommendations and declarations (as the Declaration of Helsinki, or guidelines of the Committee on Publications Ethics (COPE)).

[54] Resnik DB, Master Z. Policies and Initiatives Aimed at Addressing Research Misconduct in High-Income Countries. *PLoS Medicine*. 2013;10(3):e1001406. doi:10.1371/journal.pmed.1001406.
[55] Ibid
[56] Ibid
[57] Ibid

The most significant instruments of a more general nature include the following:

- Recommendations of the Spanish Bioethics Committee for the impulse and implementation of Good Scientific Practice in Spain[58]
- Code of good scientific practice and Committee for research integrity Instituto de Salud Carlos III[59]
- Code of Good Scientific Practice of Centro Superior de Investigaciones Científicas – CSIC[60]

The main principles included are (apart from principles such as dignity, autonomy and others indicated in the laws): the quality of research, security, confidentiality, distributive justice, the evaluation of consequences and veracity. The good practice codes include also anobligation on the researcher to declare any possible conflict of interests.

The Spanish Committee for Research Ethics, which should be created according to the law 14/2011 on Science, Technology and Innovation, but has not yet been appointed, shall also have responsibilities in this area including:

- The issuing of reports, proposals and recommendations on matters related to professional ethics in scientific and technical research;
- establishing the general principles for the development of codes of practice for scientific and technical research, which include the resolution of conflicts of interest between public and private activities. These codes will be developed by the Committees for Research Ethics and Bioethics Committee of Spain.

The codes of good scientific practice provide recommendations for dealing with scientific misconduct; however, the centers may have their own arbitration procedures for conflict resolution, as well as standards for the protection of both persons who make a complaint and the accused persons.

In **the Netherlands** a code of conduct for scientific practice has been developed by the Association of Universities (VSNU Association of Universities the Netherlands).[61] Since 1 January 2005 it has become effective in all Dutch universities. The Code of Conduct was updated in 2012. It consists of a preamble, principles and best practices. The Code includes five principles: scrupulousness, reliability, verifiability, impartiality, and independence. In 2014 a sixth principle 'responsibility'has been added.

All universities, and funding organizations, refer to the Netherlands code of conduct for scientific practice in their university code of practice. The codes of conduct of the medical

[58] Bioethics Committee, Recommendations of the Bioethics Committee in relation to Spain Momentum and Implementation of Good Scientific Practices in Spain (Recomendaciones del Comité de Bioética de España con relación al Impulso e Implantación de Buenas Prácticas Científicas en España), Madrid, 2010. http://www.comitedebioetica.es/documentacion/docs/buenas_practicas_cientificas_cbe_2011.pdf

[59] Ministerio de Economia y Competititvidad de Espana, Instituto de Salud Carlos III, Code of good scientific practice and Committee for research integrity (Codigo de Buenas Practicas Cientificas y Comité de Integridad de la Investigacion), Madrid, 14.05.2009
http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-comites/CodigoPracticasCientificas.pdf

[60] Centro Superior de Investigaciones Científicas – CSIC, Code of Good Scientific Practice (Codigo de Buenas Practicas Científicas), Madrid, 2011.
http://sac.csic.es/ccoo/textos/CBP%20%28WEB%29.pdf

[61] Association of Universities in The Netherlands, The Netherlands Code of Conduct for Scientific Practice (Nederlandse Gedragscode), The Netherlands, 2004, revision 2012,revision 2014.
www.vsnu.nl/files/documenten/Domeinen/Onderzoek/The_Netherlands_Code_of_Conduct_for_Scientific_Practice_2014.pdf

universities are more extensive as research in the medical universities needs to comply with the research codes in addition to legislation on medical research and research on human subjects. Examples of codes inspired by the code established by VSNU include:

- the UMCG code of conduct[62], that rewords the Netherlands code of conduct,
- the VUMC/AMC University[63] code of practice that also refers to the European Code of Conduct for Research Integrity by the European Science Foundation, and
- the Technical University Delft Code of ethics, a non-medical university.

The Netherlands code of conduct for scientific practice contains provisions on scientific misconduct concerning the research itself (all stages), the dissemination of scientific findings, reviewing and application for funding and jobs. Universities provide the possibility to report violations of scientific integrity and scientific misconduct. According to the Netherlands Organization for Scientific Research (NWO) fraud protocol[64]:

> "The knowledge institutions are responsible for supervising and managing the use of NWO grants. The knowledge institutions therefore bear primary responsibility for informing NWO of cases where scientific integrity has been violated. In addition cases of fraud can also come to the direct attention of NWO or be reported to NWO. In such a case NWO can, in compliance with the National Model Regulation for Complaints about Scientific Integrity of the Association of Universities in the Netherlands (VSNU), submit a complaint to the knowledge institution concerned. Besides the measures that a knowledge institution can take itself as the employer, NWO can take the measures described below in the aforementioned cases, if it is irrefutably demonstrated that scientific integrity has been violated."

7 LAWS AND REGULATIONS ON THOSE PERFORMING ETHICS ASSESSMENT

7.1 EU

All research and innovation activities within the EU are required to comply with the ethical principles in the Charter of Fundamental Rights of the European Union and European Convention on Human Rights. For Horizon 2020, specific legislation concerning ethical principles are found in Horizon 2020 Rules for Participation: Ethics Reviews (Article 14)[65], Horizon 2020 - Regulation of Establishment: Ethical principles (Article 19)[66] and the Model Grant Agreement: Ethics (Article 34).[67]

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[62] UMCG . (2013). *Researchcode University Medical Centre Groningen - basic principles for medical scientific research.* Groningen.

[63] AMC and VUMC. (2014). *Research Code, Scientific integrity at VUmc and AMC.* Opgehaald van AMC Research Code: https://www.amc.nl/web/AMC-website/Research-Code/1-Introduction.htm

[64] The Netherlands Organization for Scientific Research (NWO), NWO Fraud Protocol (NWO Fraudeprotocol) www.nwo.nl/en/news-and-events/dossiers/scientific+integrity/nwo+fraud+protocol

[65] The European Parliament and The Council, Regulation (EU) no 1290/2013 of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - The Framework Programme for Research And Innovation (2014-2020)" qnd Repealing Regulation (EC) no 1906/2006. http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf#page=10

[66] The European Parliament and the Council, Regulation (EU) no 1291/2013 of 11 december 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) and Repealing Decision no 1982/2006/EC. http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf#page=11

[67] The European Parliament and the Council, Regulation (EU) no 1290/2013 of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)" and Repealing Regulation (EC) no 1906/2006. http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf#page=10

The EU Clinical Trials Directive, defines an ethics committee as, "an independent body in a Member State, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.[68] Beyond citing the need for expertise, there are not specific guidelines on eligibility or constitution of the committee.

European organizations which engage in various type of ethics assessment include:

- European Science Foundation
- DG Research & Innovation
- EUREC
- EU-H2020 Ethics Review
- European Association for the Study of Science and Technology (EASST)
- Conference of European Schools for Advanced Engineering and Education Research (CESAER)
- European Parliament/Science and Technology Options Assessment (STOA)
- European Association of Centres of Medical Ethics (EACME)
- Virtual Institute for Responsible Innovation (VIRI)
- EGE Group,
- Council of Europe: Bioethics Committee
- Council of Europe: Committee on Culture, Science and Education
- WHO Global Health Ethics
- UN Inter-Agency Committee on Bioethics.

7.2 NATIONAL LEVEL

This section lists and provides information on the most important national institutions that engage in the process of ethics assessment in the field of research.

Austria

Advisory Board on biotechnology and genetic engineering

The Advisory Board on biotechnology and genetic engineering was established by the Genetic Engineering Act by the Ministry of Health in 1994.[69] The task of the Advisory Board on biotechnology and genetic engineering is to:

- advise the authorities in relation to basic questions of genetic engineering in relation to GMOs in contained use, the deliberate release and placing on the market of GMOs, and to genetic analysis and genetic therapy in human beings;

[68] The European Parliament and the Council, Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf

[69] The Ministry of Health, Genetic Engineering Act (Gesamte Rechtsvorschrift für Gentechnikgesetz), Austria, 1994.
http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826

- take the final decision on the revision of the "Gentechnology Codex", which summarizes the status quo of genetic engineering;
- prepare a report on the development of genetic engineering every three years, which is submitted to Austrian Parliament (starting from 1998).

The Genetic Engineering Commission consists of 28 members who are appointed by the Minister of Health for a period of five years representing the following institutions and scientific communities:

- 1 representative from the Ministry of Health;
- 1 representative from the Ministry of Women's Affairs;
- 1 representative from the Ministry of Economy;
- 1 representative from the Ministry of Labour (expert on the protection of employees);
- 1 representative from the Ministry of Environment;
- 1 representative from the Ministry of Agriculture;
- 4 representatives from the Social Partners;

- 1 representative from each scientific committee;[70]
- experts from the fields of microbiology, cell biology, virology, molecular biology, hygiene, ecology, safety technology, and sociology (nominated by the Austrian Academy of Science);
- 2 experts in the field of molecular biology (nominated by the Austrian Chamber of Commerce and the Austrian Trade Union Federation);
- 1 expert in philosophy (nominated by the Austrian Rectors' Conference);
- 1 expert in theology (nominated by the theological faculties);
- 1 medical doctor (nominated by the medical universities);
- 1 expert in environmental issues (nominated by the Environment Agency Austria);
- 1 representative of the Austrian Association for Rehabilitation (ÖAR).

The National Committee for the protection of animals used for research purposes

The National Committee for the protection of animals used for research purposes (Tierversuchskommission) was established[71] by the Act on the protection of animals used for scientific purposes, which is the transposition of the respective European Union Directive.[72]

The Austrian legislation provides for 23 members of the National Committee from the following fields of competence:

- 2 representatives from the Federal Ministry of Science and Research;
- 2 representatives from the Federal Ministry of Health;
- 1 representative from the Federal Ministry of Agriculture, Forestry, Environment and Water Management;
- 1 representative from the Federal Ministry of Labour, Social Affairs and Consumer Protection;
- 2 representatives from the University Conference (Universitätskonferenz);
- 1 representative from the Austrian Academy of Science;

[70] This relates to the three scientific committees established under the Genetic Engineering Act for admission of GMOs in the closed system, deliberate release or placing on the market of GMOs, and genetic analysis and genetic therapy in human beings.

[71] Act on the protection of animals used for scientific purposes, the National Committee for the protection of animals used for research purposes (Tierversuchskommission), Austria, 2012.
http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20008142

[72] European Parliament and the Council, Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276/33, 20.10.2010.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063

- 5 representatives from the Austrian Economic Chambers (Wirtschaftskammer Österreich);
- 5 representatives from animal protection organisations;
- 2 representatives from the Austrian Chamber of Employees (Bundesarbeiterkammer);
- 1 representative from the Austrian Chamber of Agriculture (Landwirtschaftskammer);
- 1 representative from the animal protection ombudsperson.

Research ethics committees at hospitals and medical universities
At present, there are 27 research ethics committees (RECs) in Austria of which one is presently about to merge its work with another REC.[73] Due to the fact that regular hospitals are under the legal competence of the "Bundesländer", whereas university hospitals are under the competence of the federal state, the RECs depend on different legal provisions. The Austrian legislation stipulates ethics review for clinical trials of medicinal products, medical devices, new therapies, and applied medical research. In line with the Clinical Trial Regulation, Austria has entrusted 7 RECs to deal with national multi-centre drug trials by providing a single opinion. The supervising authority for RECs is the Federal Office for Safety in Health Care.[74]

Since 1997, the Austrian RECs are represented by the "Forum of the Austrian Ethics Committees".[75] The Forum serves as contact for the legislative and the supervising authorities. The organs of the Forum are the general assembly and the board. The general assembly meets once a year during the annual Forum meeting and board meetings are scheduled once or twice a year.

As regards the composition of the ethics committee, the Austrian legislation specifies the provisions on the composition as follows:[76]

- 1 medical doctor, who is not the investigator;
- 1 specialised medical doctor for the field of research concerned;
- 1 representative of care professionals;
- 1 legal expert;
- 1 pharmacist;
- 1 representative of patient groups;
- 1 representative of disabled groups;
- 1 expert on biometrics;
- 1 person with experience in pastoral care or ethics.

Ethics Committees at the other Austrian universities
Besides Medical Universities, where the establishment of RECs is provided for by law, there is no central piece of legislation which stipulates the necessity of establishing Ethics Committees at the other Austrian universities. In total, Austria has 13 "other" Universities which offer a full programme including PhD courses.[77] At present, it is at the universities'

[73] See also: European Network of Research Ethics Committees, Austria.
http://www.eurecnet.org/information/austria.html
[74] BASG - Austrian Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen), Austria.
www.basg.gv.at/en/austrian-federal-office-for-safety-in-health-care/
[75] Forum of the Austrian Ethics Committees (Ethikkommission der Medizinischen), Austria,1997.
http://www.ethikkommissionen.at/
[76] The Ministry of Health, Genetic Engineering Act (Gesamte Rechtsvorschrift für Gentechnikgesetz), Austria, 1994.
http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441
[77] Universities of applied sciences (Fachhochschulen), offering a limited programme and the different universities of arts have not been included into the analysis.

discretion as to whether an Ethics Committee is established or not. A general trend towards establishing Ethics Committees can however be noted. The Committees are independent. Their main task relates to producing reviews on individual research projects. As a general rule, it can be noted that a negative opinion does not have a binding character, but has the legal quality of a recommendation. Nevertheless, a negative opinion hinders the researcher or research team in continuing the research at the given university. The standard practice in such a case would be to revise the project according to the opinion of the Ethics Committee.

Ethics Committee of the Seedfinancing-Programme

The Ethics Committee of the Seedfinancing-Programme of the Austrian Federal Ministry of Science, Research and Economy[78] was established in 2012. The Committee consists of five members, who are appointed by the Federal Ministry of Science, Research and Economy. They represent the fields of ethics, medicine, animal research, and law. The Committee is responsible for the review of projects regarding research in vulnerable persons, human embryo research, processing of sensible data, or animal research. 14 projects have been submitted to the Committee up to the end of 2013. The ethics assessment framework relates to the aim of the research, the methodology, possible implications of the results of the research, and compliance with national legislation.

Germany

German Ethics Council

The German Ethics Council was established on the basis of The Act on the Establishment of the German Ethics Council (Ethics Council Act - EthRG) (Deutscher Ethikrat)[79]. It is an independent body of experts that pursues "*the questions of ethics, society, science, medicine and law that arise and the probable consequences for the individual and society that result in connection with research and development, in particular in the field of the life sciences and their application to humanity."* The members of the German Ethics Council exercise their office in person and independently - they serve in their individual capacity. The Council is composed of twenty-six members specializing in *scientific, medical, theological, philosophical, ethical, social, economic and legal concerns.* Members shall include academics from the above disciplines, and in addition "persons of repute who are particularly familiar with ethical questions of life sciences".

The Central Committee for the Protection of the Ethical Principles in Medicine

The Central Committee for the Protection of the Ethical Principles in Medicine (Zentralle Kommission zur Wahrung ethischer Grundsatze in der Medizin und ihren Grenzgebieten)[80] is an independent and interdisciplinary body established at the German Medical Association (Bundesärztekammer)[81]. The mission of the Committee complies with provisions of the Basic Law, especially with the principle of the inviolability of human dignity and the protection of life and with the provisions regarding the medical profession and biomedical research set out

[78] Austrian Federal Ministry of Science, Research and Economy, Austria Wirtschaftsservice Gesellschaft (AWS), Ethics Committee of the Seedfinancing-Programme, Austria, 2012.
http://www.awsg.at/Content.Node/hochtechnologie/foerderungen/48257.php#1317

[79] Act on the Establishment on the German Ethics Council (Gesetz zur Einrichtung des Deutschen Ethikrats), Austria, 16.07.2007.
http://www.gesetze-im-internet.de/bundesrecht/ethrg/gesamt.pdf

[80] The Ethical Principles in Medicine, Central Ethics Commission of the German Medical Chamber(Zentralle Kommission zur Wahrung ethischer Grundsatze in der Medizin und ihren Grenzgebieten), Germany.
For more information: http://www.zentrale-ethikkommission.de/

[81] The German Medical Association (Bundesärztekammer), Germany.
For more information: http://www.bundesaerztekammer.de/page.asp?his=4.3569

in the World Medical Association's Declaration of Geneva[82]. The work of the Committee is regulated in the Statute of the Central Ethics Committee[83]. The Committee issues its opinions in the form of recommendations and directives. The Committee consists of 16 members, who represent different fields.

The Permanent Working Party of Research Ethics Committees in Germany

The Permanent Working Party of Research Ethics Committees in Germany[84] was established in 1983. It is involved in the process of harmonisation of activities of ethics committees as far as decision-making process and procedural matters are concerned[85]. In order to promote the cooperation between the ethics committees in Germany, the Working Party organizes meetings where ethical, scientific as well as legal matters are discussed. Moreover, the Working Group is consulted by Lands' governments and parliaments as well as the public[86]. Its activities are regulated under the Statute of the Permanent Working Party of research ethics committees in Germany[87]. According to para. 2 it is a voluntary association (*Zusammenschluss*) of German Ethics Committees dealing with evaluation (both legal and ethical) of research project on humans. It is aimed at promoting science, research and healthcare. Pursuant to para. 2(3) to fulfil its goals the Permanent Working Party shall in particular:

1. ensure proper execution of ethics committees' duties;
2. make public information on the most important problems regarding ethics and medicine;
3. strive toward harmonisation of the procedural issues among ethics committees;
4. ensure exchange of experiences and ideas;

make public its decisions.

Research ethics committees

According to section 40 (1) of the Medicinal Products Act[88], clinical trials of a medicinal product on humans may only be carried out, when "competent ethics committee has issued a favourable opinion (…) and the competent higher federal authority has given its approval". On the grounds of section 42 (2), the application for an opinion should be submitted to "the independent interdisciplinary ethics committee responsible under *Land* law for the

[82] The 2nd General Assembly of the World Medical Association, Declaration of Geneva, Geneva, 1948. http://www.wma.net/en/30publications/10policies/g1/index.html

[83] German Medical Association (Bundesärztekammer), Statut der Zentralen Kommission zur Wahrung ethischer Grundsätze in der Medizin und ihren Grenzgebieten, Germany, 20.04.2014. http://www.zentrale-ethikkommission.de/downloads/Statut20120420.pdf

[84] Permanent Working Party of Research Ethics Committees, Working Group on Medical Ethics Committees in the Federal Republic of Germany (Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland), Germany, 1982. http://www.ak-med-ethik-komm.de/

[85] Working Group on Medical Ethics Committees in the Federal Republic of Germany (Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland), Germany. For more information: http://www.ak-med-ethik-komm.de/organisation.html

[86] European Network of Research Ethics Committees, Austria. See: http://www.eurecnet.org/information/germany.html

[87] Statute of the Permanent Working Party (PWPREC) of research ethics committees in Germany (Satzung des Arbeitskreises Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland), Germany, 12.11.2005. http://www.ak-med-ethik-komm.de/documents/SatzungJuni2014.pdf

[88] Federal Ministry of Justice and Consumer Protection (*Bundesministerium der Justiz und für Verbraucherschutz*), Medicinal Products Act (The Drug Law) (Gesetz über den Verkehr mit Arzneimitteln), Germany, 24.08.1976. English: http://www.gesetze-im-internet.de/englisch_amg/medicinal_products_act.pdf German: http://www.gesetze-im-internet.de/bundesrecht/amg_1976/gesamt.pdf

investigator[89]". The committee has 60 days to issue decisions. According to article 42 (2) detailed regulations on ethics committees should be stipulated by the states (*Lands*).

Committees on Animal Experiments,
According to paragraph (§) 15 of the Animal Protection Act[90], competent authorities of the states (*Länder*) shall consult the Committees on Animal Experiments, when deciding on an approval for plans for experiments or in the event of changes in those plans. The work of the committees is regulated by each state. § 42 of the Executive Act on protection of animals used for experiments or other scientific purposes[91] determines who shall be a member of such a committee. The Majority of members come from the fields of veterinary medicine, medicine and natural science. At least one third of the committee's members must be from the animal welfare organisations. They shall be appointed based on their experience in assessing matters significant to animal protection. The remaining members of the committee should be selected by taking into consideration the suggestions of the animal welfare organisations. These members shall also have experience in the above-mentioned area.

Animal Protection Committee
The work of the Animal Protection Committee[92] is regulated by the Executive Act on the Animal Protection Committee at the Federal Ministry of Food, Agriculture and Consumer Protection[93]. The Committee is operated by the Ministry. Its aim is to consult the Ministry on matters related to animal protection. In particular, it advises on animal protection regulations. On request of the Ministry it also issues opinions on the permissions for experiments on animals. The Committee consists of 12 members.

Poland

Regional bioethics committees and the Appeal Bioethics Committee
According to Article 29 of the act of 5 December 1996 on medical professions, medical experiments can only be conducted if an independent Bioethics Committee issues a positive opinion. Committees shall include persons of both high moral authority[94] and specialist qualifications. When issuing an opinion, ethical criteria and purposefulness and feasibility of a project should be taken into consideration. Regional Bioethics Committees are established by:

- regional medical chamber (*okręgowa rada lekarska*);

[89] According to section 4 (25) of the Medical Products Act an investigator is a physician, who carries out clinical trials.
[90] Federal Ministry of Justice and Consumer Protection (*Bundesministerium der Justiz und für Verbraucherschutz*), Animal Protection Act (Tierschutzgesetz), Germany, 24.07.1972.
http://www.gesetze-im-internet.de/bundesrecht/tierschg/gesamt.pdf
[91] Federal Ministry of Food, Agriculture and Consumer Protection (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz), Executive Act on protection of animals used for experiments or other scientific purposes (Verordnung zum Schutz von zu Versuchszwecken oder zu anderen wissenschaftlichen Zwecken verwendeten Tieren), Germany, 01.08.2013.
http://www.gesetze-im-internet.de/bundesrecht/tierschversv/gesamt.pdf
[92] Federal Ministry of Food, Agriculture and Consumer Protection, Animal Protection Committee (Tierschutzkommission beim Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz), Animal Protection Committee regulated by the Executive Act on the Animal Protection Committee, Germany.
http://www.gesetze-im-internet.de/englisch_gg/englisch_gg.html
[93] Federal Ministry of Food, Agriculture and Consumer Protection (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz), Executive Act on the Animal Protection Committee at the Federal Ministry of Food, Agriculture and Consumer Protection (Verordnung über die Tierschutzkommission beim Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz), Germany, 23.06.1987.
http://www.gesetze-im-internet.de/bundesrecht/tierschkomv/gesamt.pdf
[94] „High moral authority" is the phrase used in Article 29 of the Act on medical profession (in Polish *„wysoki autorytet moralny*"). The law however does not specify how the level of moral authority should be assessed.

- rector of a medical university;
- director of a medical research and development units (*dyrektor medycznej jednostki badawczo-rozwojowej*).

Appeal Bioethics Committee is to be constituted by the Minister of Health.

The main act regulating the work of Regional and Appeal Bioethics Committees is the executive act of the Minister of Health and Social Care of 11 May 1999 on specific regulations regarding the constitution, funding and operation of bioethics committees[95]. Pursuant to § 3, the term of Regional Ethics Committees is 3 years. Members shall be:

- specialist physicians;
- representatives of other professions, in particular clerics, philosophers, lawyers, pharmacists, nurses (one from each profession).

Members shall have at least ten years of experience in their fields. The committees consist of 11-15 members. Should a person other than a physician be the employee of the institution that established the Regional Bioethics Committee, he or she cannot become the member. The chairperson shall be a physician and the vice-chairperson shall be from another profession. Members can be released from duties, if he or she resigns or does not attend the committee's meetings. As a general rule the committees make decisions by voting.[96]

As far as membership in Appeal Bioethics Committees is concerned, this matter has not been regulated. This is also the case for issues regarding the special training of both regional and Appeal Bioethics Committees' members.

The following parties may appeal the opinion of the Regional Bioethics Committee:

- the applicant;
- director of the Health Centre, where the experiment is to be conducted;
- a/the competent Bioethics Committee.

National Ethics Committee for Experiments on Animals and Local Ethics Committees for Experiments on Animals

Until now the functioning of ethics committees for experiments on animals has been regulated by the executive act of the Minister of Science and Digitalization of 29 June 2005 on the National Ethics Committee for experiments on animals and Local Ethics Committees for experiments on animals[97]. This executive act was adopted on the basis of the former Animal Research Act. However on 15 January 2015, a new act was passed (The Act on Protection of

[95] Minister of Health and Social Care (Minister Zdrowia i Opieki Społecznej), Executive Act of the Minister of Health and Social Care of 11 May 1999 on specific regulations regarding constituting, funding and operating of bioethics committees (Rozporządzenie Ministra Zdrowia i Opieki Społecznej z dnia 11 maja 1999 r. w sprawie szczegółowych zasad powoływania i finansowania oraz trybu działania komisji bioetycznych), 11.05.1999.
http://isap.sejm.gov.pl/DetailsServlet?id=WDU19990470480

[96] See the rules of proceedings of particular committes, for example:
www.komisjabioetyczna.pl/regulamin.php, point 12.

[97] Minister of Science and Digitalization (Minister Nauki i Informatyzacji), Executive Act of the Minister of Science and Digitalization of 29 June 2005 on the National Ethics Committe for Experiments on Animals and Local Ethics Committees for Experiments on Animals (Rozporządzenie Ministra Nauki i Informatyzacji z dnia 29 lipca 2005 r. w sprawie Krajowej Komisji Etycznej do Spraw Doświadczeń na Zwierzętach oraz lokalnych komisji etycznych do spraw doświadczeń na zwierzętach), Poland, 29.06.2005.
http://isap.sejm.gov.pl/DetailsServlet?id=WDU20051531275

Animals Used for Scientific and Educational Purposes)[98], which implements the provisions of the Directive 2010/63/EU[99]. At the time of writing of this report, no draft executive acts have been presented that lay down the details of how the committees would operate.

The Act on Protection of the Animals Used for Scientific and Educational Purposes foresees the establishment of the following bodies:

a. National Ethics Committee that would consist of:
    - 9 members from the fields of biology, pharmaceutical sciences, medicine, agricultural sciences with at least the degree of Ph.D. and both knowledge and experience with animal research;
    - 3 members from humanities or social sciences, especially from the fields of philosophy, ethics or juristic science;
    - 3 members of non-governmental organisations dealing with animal protection.
b. Local Ethics Committees:
    - 6 members from the fields of biology, pharmaceutical sciences, medicine, agricultural sciences, veterinary sciences with at least the degree of Ph.D. and both knowledge and experience with animal research;
    - 3 members from humanities or social sciences, especially from the fields of philosophy, ethics or juristic science, including one member of a non-governmental organisation, that deals with the protection of patients' rights;
    - 3 members of non-governmental organisations dealing with animal protection

The National Ethics Committee in particular:
- gives opinions regarding matters concerning research on animals,
- drafts rules of good scientific practice,
- presents the reports on undertaken control procedures,
- cooperates with the European Council to develop new, less harmful forms of research,
- gives information on alternative methods of research,
- appoints members of the local committees,
- presents the information on the research permissions granted.

Local Ethics Committees are responsible for:
- granting permissions for an experiment,
- carrying out retrospective assessment,
- providing the public with summaries of the experiments.

Committees and commissions established at the Polish Academy of Sciences
Article 39 of the act of 30 April 2010 of the Polish Academy of Sciences[100] establishes the Ethics in Science Commission at Polish Academy of Sciences (*komisja do spraw etyki w*

[98] National Ethics Committee for Experiments on Animals and Local Ethics Committees for Experiments on Animals, Act of 15 January 2015 on protection of animals used for scientific and educational purposes (ustawa z dnia 15 stycznia 2015 r. o ochronie zwierząt wykorzystytwanych do celów naukowych lub edukacyjnych), Poland, 15.01.2015. http://orka.sejm.gov.pl/opinie7.nsf/nazwa/2709_u/$file/2709_u.pdf

[99] European Parliament and the Council, Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes, 20.10.2010. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063

[100] Polish Academy of Sciences, Act of 30 April 2010 on the Polish Academy of Sciences (Polskiej Akademii Nauk), Poland, 30.04.2010. http://isap.sejm.gov.pl/DetailsServlet?id=WDU20100960619

nauce). It issues opinions on matters concerning breaches of ethical principles in science by employees of universities, scientific units of the Academy and research institutions. The opinions in question are binding. They are issued by panels of three members. The Commission can, on its own initiative, refer matters regarding such breaches to competent disciplinary committees. Its task is also to draw up The Ethical Code of a Researcher[101] and to disseminate standards of scientific integrity.

There is no National Ethics Committee in Poland. The Committee of Bioethics at the Polish Academy of Sciences performs, to some extent, the function of such a committee.[102] The Committee was established in 2011. It is an advisory body. Its main task is to identify and analyze ethical problems resulting from the development of the sciences, especially the biomedical sciences, and their impact on the social, political and legal spheres. The Committee puts particular emphasis on the consequences of scientific progress for the development of the country, as well as on cases of negligence in the practice of scientific and social life.[103] The Committee focuses on ethical implications of technological progress in medicine and biology. It does not deal with environmental issues or the question of animal rights. It concentrates on the ethical questions it finds to be most important in the current environment in Poland. For this reason, moral issues in medicine and health care policy are the main focus of the Committee.

Spain

The Spanish Bioethics Committee

The Spanish Bioethics Committee was created through Law 14/2007 as a "collegiate, independent and consultative professional body, which will develop its responsibilities, with full transparency, on materials related to the social and ethical implications of Biomedicine and Health Sciences". The Committee was established on October 22nd 2008 and forms part of the Ministry of Health, Social Services and Equality. Its mission is to issue reports, proposals and recommendations for public authorities at state and regional level on matters related to the ethical and social implications of biomedicine and health sciences. Equally, it is responsible for establishing general principles for the production of codes of good practice in scientific research and for representing Spain in supranational and international forums and bodies involved in bioethics. The Committee's ethical assessment reflects its members' individual moral and expertise, taking into consideration the values of the Spanish society and the law. These recommendations and opinions are not binding. It is composed by twelve members, elected from scientific, medicine, legal and bioethical experts. Its members are nominated by several Ministries and Autonomous Communities through the Inter-regional Council of the National Health System and the Ministries of Health, Justice, Industry and Economy.

The National Commission on Assisted Human Reproduction

[101] Ethics in Science Commission at Polish Academy of Sciences, The Ethical Code of a Researcher (Kodeks etyki pracownika naukowego), 2012. www.instytucja.pan.pl/images/stories/pliki/Komisja_ds_Etyki_Nauce/dokumenty/Kodeks_etyki_pracownika_naukowego_31.12._2012.pdf

[102] Ministry of Health, the Committee of Bioethics at the Polish Academy of Sciences (Komitet Bioetyki przy prezydium PAN), Poland.
http://www.bioetyka.pan.pl/images/stories/Pliki/KOMITET_BIOETYKI_-_program.pdf

[103] The Committee of Bioethics at the Polish Academy of Sciences (Komitet Bioetyki Polskiej Akademii Nauk, PAN), Poland.
http://www.bioetyka.pan.pl/

The National Commission on Assisted Human Reproduction is a consultative body, under the Ministry of Health, Social Policy and Equality, aimed at providing guidance on the use of assisted human reproduction techniques. Its decision is binding. The Commission collaborates with public authorities concerning diagnostic, therapeutic and scientific purposes in the matter of human assisted reproduction.

The Commission of Guarantees for the Donation and Use of Human Cells and Tissues
The Commission of Guarantees for the Donation and Use of Human Cells and Tissues is a consultative body aimed at providing advice and guidance on research and experimentation on biological samples of human embryonic nature. In addition, the Commission contributes to the updating and dissemination of scientific and technical knowledge in this field. Its decision is binding.

Some Autonomous Communities (Basque Country, Catalonia, Aragon, Andalusia, Galicia, and Valencia) have launched their own bioethics committees. Their ethical assessment reflects their members' individual moral and expertise, taking into consideration the values of the Spanish society and the national and regional law.

Research ethics committees (RECs)
RECs are the oversight bodies of methodological adequacy, ethical acceptability and regulatory compliance regarding research on human subjects. Local RECs need to be accredited.[104] For the accreditation of a REC the following criteria must be considered: independence and impartiality of its members with regard to promoters and researchers in biomedical research projects, as well as its cross-disciplinary composition. The main function of these committees is to evaluate the ethical aspects of research, but they also review the scientific and methodological aspects[105]. RECs that oversee clinical trials need to be specially accredited. The Royal Decree on clinical trials indicates the composition of RECs accredited for clinical trial:[106] at least 9 members, experts in the methodological, ethical and legal aspects of research, pharmacology and clinical practice. The members of the committee must include medical doctors (including a clinical pharmacologist), a hospital pharmacologist, and a graduate in nursing. At least one member must be independent of the centres where the research projects are carried out. At least two members must come from outside the health professions, one of which must have graduated in Law. The composition of other RECs is not legally established. Similarly, the procedure to obtain the review of the REC is not legally established and can vary in each one. In drug clinical trials, it is necessary to include the authorization of the Spanish Agency for Medicines and Health Products, Ministry of Health, Social Services and Equality[107] and the report from the REC. Besides RECs, universities may create committees that oversee any type of research done within the university, however the rules of how such committees are not established by the law.

[104] Art. 12: "The Research Ethics Committees of those centres that undertake biomedical research shall be duly accredited by the corresponding authority of the autonomous community to which they belong or, in the case of centres that belong to the General Administration of the State, by the corresponding authority of such, in order to assure its independence and impartiality.", Law 14/2007 of 3 July 2007 on Biomedical Research, Spain, 03.07.2007.
[105] Art. 12.2: REC have the following functions: "b)Weighing the methodological, ethical and legal aspects of the research project"; art. 16: "The evaluation must (..) take into account the scientific suitability of the project, its relevance, feasibility and appropriateness of the principal researcher and the research team", Law 14/2007 of 3 July 2007 on Biomedical Research, Spain, 03.07.2007.
[106] Art. 12 RD 223/2004, for which clinical trials are regulated with medication (Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos), Spain, 06.02.2004.
http://www.boe.es/buscar/doc.php?id=BOE-A-2004-2316
[107] Spanish Agency for Medicines and Health Products, Resolution of 5 June 2014, Spain, 10.06.2014.
http://www.boe.es/boe/dias/2014/06/10/pdfs/BOE-A-2014-6169.pdf

Ethics Committees that issue opinions on animal experimentation

Ethics Committees that issue opinions on animal experimentation need to have the expertise and resources needed to carry out the functions. Moreover, they should not demonstrate any conflict of interest in the performance of their duties.[108] The ethics committee must include researchers and other scientific members not directly related to the project, in addition to a person with experience and knowledge in animal welfare who has no direct relation with the animal facility centre or the project. [109]

Serbia

The Ethics Board of Serbia

The Ethics Board of Serbia (EBS) is the highest body that deals with ethical issues in Serbia. It is established by the Law on Health Care. EBS has a consultative and strategic role, but no legally binding power. The Law on Health Care defines the structure and sphere of competence of the EBS. It is a professional body, which looks after the provision and implementation of health care on the national level and compliance with the principles of professional ethics. The Government nominates and relieves the chairperson and the members of the EBS at the behest of the minister. The EBS consists of nine members who are elected from the ranks of prominent experts who have major scientific publications, as well as contributions in the areas of health care, professional ethics of health care practitioners and of humanistic sciences. The members of the EBS may not be the persons elected, appointed or nominated for the function within a government authority, an authority of the territorial autonomy or local self-government, a person nominated by the bodies of the organizations dealing with health insurance, or the bodies of health care facilities, institutes of advanced education, associations of health care practitioners, the Serbian Medical Society, or association of health care facilities. The tenure of the members of the EBS is five years. The funds for the work of this Board are provided in the budget of the Republic. The EBS adopts its own rules of procedure.

Ethics committees

The Law on Health Care also establishes Ethic committees (EC) on the level of institutions (at clinical centres, at universities, at research institutes). These committees oversee, among other duties, medical research, clinical trials, research in natural sciences (mostly in biology). Unlike EBS, ECs have a more practical role, because they analyse applications for R&I and grant permission for the conduct of research and the implementation of innovations in medical practice. If the researcher is dissatisfied with the assessment, he or she may appeal to the EBS.

The Law on Health Care and Law on Medicines and Medical Devices define the structure and sphere of competence of the EC. The EC is a professional body that monitors the provision and implementation of health care according to the principles of professional ethics. The director of the health care institution nominates the EC at the behest of the professional council. The members of the EC are appointed from the ranks of employed health care practitioners in the health care facility and citizens who graduated from the faculty of law who live or work in the territory in which the health care facility has been founded. The number of members of the EC is regulated by the articles of association of the health care facility. The EC of a health care facility in which clinical trials of medicines and medical devices in stock are conducted, has - in addition to other members- at least three medical specialists with a PhD degree in the branch of medicine specific of the facility, who should be

[108] Article 43, Royal Decree 53/2013 on Animal experiments, Spain, 01.02.213.
[109] Article 39, Royal Decree 53/2013 on Animal experiments, Spain, 01.02.213.

experienced in the scientific and medical assessment of the results obtained in clinical trials of medicines and medical devices, as well as in ethical principles of clinical trials. In the course of deciding on clinical trials of medicines or medical devices, the EC can request the professional opinion of prominent experts who are not members of the EC in specific fields necessary for making a decision on clinical trial.

The Ethics Council for the welfare of animals used in animal testing

The Ethics Council for the welfare of animals used in animal testing is in fact a special working group established by the Minister, in accordance with the regulations governing the civil service, in order to discuss professional issues, provide expert opinions and participate in the implementation of terms of reference in the field of animal welfare. This Council has only an advisory role and has no binding power. It has a strategic role by:

1) providing advice in the area of Ethics and Animal Welfare in conducting experiments and genetic modification and manipulation of animals;
2) providing expert opinion on the ethical and scientific justification of the experiments, as well as the cessation of animal testing;
3) providing advice in order to harmonize the work of ethics commissions for protection of welfare of animals used in animal testing;
4) providing expert opinion on the execution of specific and invasive experiments;
5) participating in the development and promotion of alternative methods of conducting the experiments;
6) reporting to the minister annually on its work and the status of welfare of animals used in animal testing, as well as performing other duties in accordance with the law.

Ethics Commission for Protection of Welfare of Animals used in Animal Testing

Scientific and research institutions and other legal entities which carry out animal testing are obliged, within their organization or together with other R&D organizations or legal entities which carry out animal testing, to establish an Ethics Commission for Protection of Welfare of Animals used in Animal Testing. The Ethics Commission consists of a veterinarian surgeon, a veterinarian with experience in the breeding of animals to be used in testing, experts with experience in the application of statistics in research, representatives of associations or organizations whose objectives are focused on animal welfare, as well as researchers from related scientific fields. At least one third of the members of the Ethics Commission must be persons who are not employed in the scientific organization or other legal entity which conducts animal testing. A member of the Ethics Council cannot simultaneously be a member of the Ethics Commission. Members of Ethic Commission are not obliged to receive any kind of training.

<u>The Netherlands</u>

Central Committee on Research Involving Human Subjects (CCMO)

CCMO is the body responsible for implementing the Medical Research Involving Human Subjects Act (WMO). Its tasks consist of overseeing the operations of the accredited medical ethical reviewing committees (MRECs) and reviewing specific fields of research as laid down in the WMO and the Embryo Act. CCMO acts as the competent authority for the (marginal) review of research with a medicinal product and it maintains an overview of all WMO research reviewed in the Netherlands since 1 December 1999 which is presented in annual reports. CCMO functions as an administrative body in the case of administrative appeals against the decision of an MREC, and plays a key role as a provider of information on

medical research with human subjects carried out in the Netherlands.[110] The committee members of the CCMO are appointed by the minister on the basis of expertise. They carry out their work for the CCMO alongside their regular positions and also regularly offer expertise to other bodies. If a member has various roles and contacts, it does not necessarily have to pose a problem for their activities for the CCMO. However, their interests must be transparent.[111] The committee consists of a maximum of fifteen members along with their deputies. It consists of one or more physicians, and people with expertise in the fields of embryology, pharmacology, pharmacy, nursing, behavioural science, jurisprudence, the methodology of scientific research and the ethics thereof, as well as a person who reviews scientific research specifically from the perspective of the research subject. Furthermore, the committee is extended with a 'fundamental' scientist, from the basic sciences such as mathematics, chemistry, physics, . The meetings are attended by an observer of the Ministry of Health, Welfare and Sport.[112]

Medical Research Ethical Committees (MRECs)

24 accredited MRECs in the Netherlands review medical/scientific research proposals. The majority are linked to an institution such as an academic medical center or a hospital. An accredited MREC determines the region it covers with regards to the review of research. This is known as the "working environment".[113] In practice, the MRECs review for the whole of the Netherlands. MRECs also review the research proposals of private companies. For instance, the MREC of Wageningen University reviews the research proposals of Unilever, for research that is carried out in the Netherlands. The MREC can charge for the costs incurred during the review. Accredited MRECs each have their own tariffs.

Human Research Ethical Committees (HREC)

Non-medical universities do not have Medical Research Ethical Committees but have rather Human Research Ethical Committees (HRECs). The Human Research Ethics Committee examines research that is deemed to exhibit more than a "minimal risk" for volunteers who participate in research. The Delft Human Research Ethics Committee (TU DELFT 2015)[114] expects the following qualities of ethical human research:

- Are subjects subjected to a greater than acceptable risk given the potential benefits?
- Have subjects or participants been adequately informed and provided free consent?
- Are vulnerable populations targeted and have special precautions been taken to protect them?
- Is the study properly expressed scientifically and does it clearly state its potential harms and benefits?

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[110] Central Committee on Research Involving Human Subjects, CCMO) (Centrale Commissie Mensgebonden Onderzoek, CCMO), The Netherlands.
http://www.ccmo.nl/en/tasks-of-the-ccmo

[111] Central Committee on Research Involving Human Subjects, CCMO) (Centrale Commissie Mensgebonden Onderzoek, CCMO), The Netherlands.
http://www.ccmo.nl/en/independance

[112] Central Committee on Research Involving Human Subjects, CCMO) (Centrale Commissie Mensgebonden Onderzoek, CCMO), The Netherlands.
http://www.ccmo.nl/en/members

[113] Central Committee on Research Involving Human Subjects, CCMO) (Centrale Commissie Mensgebonden Onderzoek, CCMO), Accredited MRECs. The Netherlands.http://www.ccmo.nl/en/accredited-mrecs?51d2da84-cef8-490b-907c-4846525ed690

[114] TU Delft Human Ethics Committee. (2014). *Research ethics application.* Opgehaald van Delft University - Research Ethics: http://www.tudelft.nl/en/about-tu-delft/strategy/integrity-policy/scientific-integrity-committee/research-ethics/

These considerations arise out of international agreements such as the Helsinki Declaration, in which nations around the world agree to oversee medical research using humans and apply the Nuremberg Principles to all such research. As TU Delft is concerned with ethics in all contexts, they apply these principles even to non-medical human research conducted at the university.[115]

Committees reviewing animal experimentation
Universities and research institutes require a license before research involving animals can be performed. The Central Committee on Experiments on Animals (Centrale Commissie Dierproeven, CCD) performs the legally required ethical evaluation and authorizes the project. The project proposal first requires approval by the animal experiment ethics committee DEC (Dierproeven Ethiek Commissie). The purpose of the project proposal is to inform the members of both the DEC and the CCD of the proposed procedures and the project's scientific or social relevance in a realistic and understandable manner. The evaluation of the ethical acceptability of the proposed procedures requires a justification of the choices that were made during the design of the project (CCD 2015). The composition of the DEC is not specified in the law.

Legislatively, **France** has two types of research ethics committees, one for research involving animals and another for research involving humans.

In addition, the National Consultative Ethics Committee for health and life sciences (*Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé* or *CCNE*) was created by the presidential decree n°83-132 on February 23th1983 (Décret n°83-132 du 23 février 1983 portant création d'un Comité consultatif national d'éthique pour les sciences de la vie et de la santé)[116]. The CCNE is a strictly consultative body[117]. CCNE's mission is to provide advice on ethical issues and social issues raised by the progress of science in the fields of biology, medicine and health and can publish recommendations on matters within its competence. CCNE is required to organize public debates at least every five years and prior to any reform bill on ethical or social issues raised by advances in biology, medicine and health. CCNE is also responsible for documentation and the provision of information to the public on questions raised by the life sciences and health. However, CCNE does not assess research projects.

As to research involving humans, the Committees for the Protection of Persons (*Comités de Protection des Personnes* or *CPP*) were instituted by the Law No. 2004-806 of 9 August 2004 on public health policy (Loi n° 2004-806 du 9 août 2004 relative à la politique de santé publique)[118]. Theyreplaced the Advisory Committees for the Protection of Persons in Biomedical Research (Comités consultatifs de protection des personnes dans la recherche biomédicale or CCPPRB) that had been instituted by the Law No. 88-1138 of 20 December 1988, called law Huriet, relating to the protection of persons who lend themselves to

115 [115] TU Delft Human Ethics Committee. (2014). *Research ethics application.* Opgehaald van Delft University - Research Ethics: http://www.tudelft.nl/en/about-tu-delft/strategy/integrity-policy/scientific-integrity-committee/research-ethics/

[116] Decree No. 83-132 of 23 February 1983 establishing a National Consultative Ethics Committee for Life Sciences and Health, France, 23.02.1983.
http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000687778

[117] National Consultative Ethics Committee for health and life sciences (Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé or CCNE), France, 1983.
http://www.ccne-ethique.fr/en/pages/functionning.html#.VMvKhy7h134

[118] Law no. 2004-806 of 9 August 2004 on public health policy, France, 09.08.2004.
http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000787078

biomedical research (*Loi n°88-1138 du 20 décembre 1988 diteHuriet relative à la protection des personnes qui se prêtent à des recherchesbiomédicales*)[119]. The CPPs, which have territorial jurisdiction, are formally designated to deliver opinions on research protocols submitted to them (in practice, to assess and to give an opinion on research protocols submitted to them). Some types of research can only be carried out after a favourable opinion (i.e. ethical clearance) of a CPP.

A whole chapter is devoted to the CPPs in the legislative part but also in the regulatory part of the French Public Health Code (PHC) in which both the 1988 and the 2004 laws have been codified. Provisions of the latter chapter relate to the CPP accreditation criteria, the composition and the appointment of its members, its organization and operation, and its role in the assessment and monitoring of research. Each CPP has a registered office in a public health establishment.

Legislation establishes other public organizations which are not devoted to ethical assessment but either interact with CPPs in the process of authorization of a research project or authorize specific types of research projects not assessed by CPP:

The French National Agency for Medicines and Health Products Safety (*Agence française de sécurité sanitaire des produits de santé* or *ANSM*)[120] conducts expert assessment of healthcare products and acts as a decision-making body in the field of sanitary regulation.

The National Commission on Informatics and Liberties (*Commission nationale de l'informatique et des libertés* or *CNIL*) **and the Advisory Committee on Research Data Processing in the Health Field** (*Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé*or *CCTIRS*)[121] deal with data protection.

The Biomedicine Agency (*Agence de Biomédecine*) has jurisdiction over research on embryos and stem cells, organ transplantation, medical assisted procreation

The High Council of Biotechnologies (Haut Conseil des biotechnologies or HCB) has expertise in biotechnologies

For example, the overall authorization process of a biomedical research project involves in parallel the ANSM, a CPP, in some cases the CCTIRS and the CNIL. For a biomedical research project to start, three separate authorizations and/or favourable opinions from these four organizations are currently required. These three institutions therefore perform four separate assessments on different axes. ANSM is concerned with the safety of persons and the products used. The CPP looks at scientific (methodological) and ethical aspects of the protocol. The CNIL and the CCTIRS are concerned with personal data security.

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[119] Law no. 88-1138 of 20 December 1988 on on the protection of persons who consent to biomedical research, France, 20.12.1988.
http://legifrance.gouv.fr/affichTexte.do;jsessionid=72B904A11C6E6DDB0A906A31AE7A9D02.tpdjo08v_1?cidTexte=JORFTEXT000000508831&dateTexte=20150123

[120] National Agency for Medicines and Health Products Safety (l'Agence nationale de sécurité du médicament et des produits de santé, ANSM), France.
http://ansm.sante.fr/

[121] The National Commission on Informatics and Liberties (Commission nationale de l'informatique et des libertés or CNIL) and the Advisory Committee on Research Data Processing in the Health Field (Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé or CCTIRS), France.
http://www.enseignementsup-recherche.gouv.fr/cid20537/cctirs.html

The establishment by the legislation of ethical reflection spaces (*espaces de réflexion éthique*) (i.e. think tanks on ethics) is also worth mentioning. They are physical locations for training, documentation, meeting and interdisciplinary dialogue on ethical issues in the field of health. They are also regional or interregional observatories regarding ethics. However, to date, these ethical reflection spaces are underdeveloped and do not play a significant role in the assessment of research and innovation.

For research involving animals, French regulations establish three types of organizations:

The Ethics Committees for Animal Experimentation (Comités d'éthique en experimentation animale), which act as institutional review boards for protocols reviewing the use of animals in research.

The National Committee for Consideration of Ethics in Animal Experimentation (Comité National de Réflexion Ethique sur l'Expérimentation Animale or CNREEA), whose role is to issue opinions on the ethical issues raised by animal testing. As such, it has drafted[122] a national charter on ethics and ethics animal experiments and made proposals on its implementation. Bearing in mind, that any ethics committee for animal experimentation should take into account the principles established by the Charter (Art R.214-124 of the Rural and Maritime Fisheries Code).

The National Commission of Animal Experimentation (Commission nationale de l'expérimentation animale) houses the secretariat of the National committee for consideration of Ethics in Animal Experimentation, and advises on matters of policy related to animal experimentation. Pursuant to Articles R. 214-116 et seq of the Rural and Maritime Fisheries Code (Code rural et de la pêche maritime), the committee gives advice on any contemplated change in laws or regulations on animal experimentation. It can also make any proposals it deems appropriate in the field of animal experimentation.

8 CORPORATE SOCIAL RESPONSIBILITY

8.1 EU

European companies have no general legal obligation under EU law to adopt CSR policies or to report on them. Indeed, most references to CSR consider the actions and responsible activities beyond what the law requires in order to achieve social and environmental objectives.[123] In order to facilitate the adoption of CSR policies, either by companies or member states, the European Union has actively sponsored studies or commissioned reports. Chief among these efforts is the 2013-2014 European Commission peer review of EU member States' activities on CSR. The European Commission adopted a formal strategy for addressing CSR, as outlined in the Communication A renewed EU strategy 2011-14 for Corporate Social Responsibility (COM (2011) 681)[124] , highlighting in its agenda:

[122] The National Committee for Consideration of Ethics in Animal Experimentation (Comité National de Réflexion Ethique sur l'Expérimentation Animale or CNREEA).
http://www.enseignementsup-recherche.gouv.fr/cid70598/l-encadrement-reglementaire-de-l-utilisation-d-animaux-a-des-fins-scientifiques.html

[123] European Commission, 2013-2014 European Commission peer review of EU member States' activities on CSR.
http://ec.europa.eu/social/main.jsp?catId=331

[124] European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A renewed EU strategy 2011-14 for Corporate Social Responsibility, COM(2011) 681 final, Brussels, 25.10.2011.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0681:FIN:EN:PDF

The Commission's CSR agenda for action is:

1. Enhancing the visibility of CSR and disseminating good practices
2. Improving and tracking levels of trust in business
3. Improving self- and co-regulation processes
4. Enhancing market reward for CSR
5. Improving company disclosure of social and environmental information
6. Further integrating CSR into education, training and research
7. Emphasising the importance of national and sub-national CSR policies
8. Better aligning European and global approaches to CSR. [125]

The European Commission strategy is predicated by the principles found in,

- United Nations Global Compact
- United Nations Guiding Principles on Business and Human Rights
- ISO 26000 Guidance Standard on Social Responsibility
- International Labour Organization Tripartite Declaration of Principles concerning Multinational Enterprises on Social Policy
- OECD Guidelines for Multinational Enterprises

The European Commission also tracks national CSR policies in its CSR Compendium[126] most recently published in 2014. With regards to research and innovation, the EC has used the establishment of European CSR awards to encourage responsible partnerships between businesses and non-business organizations. Additionally, it has published a *Recommendation on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations*.[127]

8.2 NATIONAL LEVEL

The Austrian business council for sustainable development is **Austria**'s leading platform for Corporate Social Responsibility (CSR) and Sustainable Development. The association was formed in October 2007. The platform is led by businesses and is financed through the contributions of its member companies, the Austrian Federal Economic Chamber,[128] the Federation of Austrian Industry,[129] the Federal Ministry of Science, Research and Economy,[130] the Federal Ministry of Labour, Social Affairs and Consumer Protection[131] and the Federal Ministry of Agriculture, Forestry, Environment and Water management.[132] The council's most important activities are related to leadership on CSR and sustainability, exchange of best practices, knowledge transfer and education, as well as the establishment

[125] European Commission, Enterprise and Industry, Corporate Social Responsibility (CSR). http://ec.europa.eu/enterprise/policies/sustainable-business/corporate-social-responsibility/index_en.htm

[127] European Commission, Recommendation 2014/179/EU of 9 April 2014 on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations, 09.04.2014.

[128] The Austrian Federal Economic Chamber (Wirtschaftskammer Österreich), Austria. https://www.wko.at/Content.Node/iv/index.html

[129] The Federation of Austrian Industry (Industriellen Vereinigung), Austria. http://www.iv-net.at/

[130] The Federal Ministry of Science, Research and Economy (Bundesministerium für Wissenschaft, Forschung und Wirtschaft), Austria. http://www.bmwfw.gv.at/Seiten/default.aspx

[131] The Federal Ministry of Labour, Social Affairs and Consumer Protection (Bundesministerium für Arbeit, Soziales und Konsumentenschutz), Austria. http://www.sozialministerium.at/site/

[132] The Federal Ministry of Agriculture, Forestry, Environment and Water management (Das Bundesministerium für Land- und Forstwirtschaft, Das Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft), Austria. http://www.bmlfuw.gv.at/

and administration of a national CSR network. The council has published guidelines which aim to help businesses to recognise their social responsibility. The guidelines are intended for use by any Austrian company, large or small, and list objectives for responsible business activity based on five fields of action:[133] leadership, marketplace, workforce, environment, society. These guidelines differ from the EC definition of CSR, as they do not include the dimension of ethics.[134] Austria has not produced an Action Plan on Business and Human Rights as advised by the UN Working Group on the issue of human rights and transnational corporations and other business enterprises. Neither has Austria committed to elaborating such an Action Plan.[135]
Directive 2003/51 on the annual and consolidated accounts of certain types of companies, banks and other financial institutions and insurance undertakings[136] was transposed into Austrian legislation and obliges joint stock companies and groups of companies to report on environmental and employee issues in their annual status reports.

The German federal government adopted the Sustainability Strategy in 2002 On October 6, 2010, the German Federal Government adopted the "CSR in Germany" Action Plan to address issues including climate change, good and fair working conditions, globally binding labor and social standards, the fulfillment of social responsibility through civic engagement and corporate citizenship and sustainable consumption.[137] The government promotes the implementation of CSR strategies; however, CSR by definition remains voluntary. At the same time, according to NGO reports,[138] the German government blocked the reform of the EU Accounting and Transparency Directive for some time. Under the new directive, listed enterprises will in future have to disclose their project-related payments to government worldwide. Moreover, according to NGOs the German report also opposed the proposed duty to disclose non-financial information.[139] As regards disclosure of non-financial information, the German Commercial Code requires companies to disclose a management report. The management report apart from the key indicators of financial performance must include information about environmental and employee matters if they are essential for the understanding of the course of business and the position of the company (German Commercial Code, section 289). Other mandatory disclosures do not exist in Germany. Companies may disclose other or more detailed information in CSR reports on voluntary basis. Germany has not developed a National Action Plan on Business & Human Rights.

In **Poland,** on the basis of an act of 9 July 2014, Minister of Economy appointed a group for corporate social responsibility issues (the group operated in the past, between 2009 and 2013

[133] Success and Social Responsibility (Erfolg mit Verantwortung), Austria. https://www.respact.at/leitbild/en/home
[134] EC definition of CSR: "Respect for applicable legislation, and for collective agreements between social partners, is a prerequisite for meeting that responsibility. To fully meet their corporate social responsibility, enterprises should have in place a process to integrate social, environmental, ethical, human rights and consumer concerns into their business operations and core strategy in close collaboration with their stakeholders (...)".http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0681:FIN:EN:PDF
[135] UN Working Group on the issue of human rights and transnational corporations and other business enterprises, Action Plan on Business and Human Rights
http://www.ohchr.org/EN/Issues/Business/Pages/NationalActionPlans.aspx
[136] The European Parliament and the Council, Directive 2003/51 of 18 June 2003 on the annual and consolidated accounts of certain types of companies, banks and other financial institutions and insurance undertakings, 17.07.2003.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:178:0016:0022:en:PDF
[137] Federal Ministry of Labour and Social Affairs, CSR Made in Germany, January 2012, p. 5.
http://www.csr-in-deutschland.de/fileadmin/user_upload/Downloads/BMAS/CSR-IN-GERMANY_Broschuere_2012.pdf
[138] Heydenreich, Cornelia, Paasch, Armin and Kusch Johanna, 2014 Report – Executive Summary Global Business and Human Rights Putting Germany to the Test, Bischöfliches Hilswerk, February 2014, p.5. http://germanwatch.org/en/download/8874.pdf
[139] ibid.

however was deactivated).[140] A representative of the Minister responsible for issues of the economy with the rank of Under-Secretary of State presides over the operations of the Group. The Ministry of Economy runs a government website.[141] As regards annual financial reporting, Article 49 point 3 of the Accounting Act[142] stipulates that companies should include information on non-financial indicators, such as information relating to environment or employment matters, if it is relevant to the assessment of the company's performance.
Other forms of reporting take place on a voluntary basis and companies are not obliged to have a CSR strategy by national law. In November 2009, the Warsaw Stock Exchange launched Poland's first index of socially responsible companies.

In **Serbia**, there is no Ministry or separate organizational unit within a Ministry that deals exclusively with the promotion and development of CSR or business ethics, but the Government, through the Ministry of Labour and Social Policy, has taken steps to establish a public policy in this area. The government is also taking measures to incorporate CSR issues in laws and regulations, as part of the process of accession to the European Union. One of these measures is the adoption of the Strategy for the Development and Promotion of CSR in the Republic of Serbia for the period 2010 – 2015.[143] Furthermore, there is an Association of Corporate Directors of Serbia, established based on best international practices, whose members are CEOs or board members of corporations and who commit to an Ethics Code and espouse OECD Principles of Corporate Governance.[144] The Serbian Chamber of Commerce has also adopted a Corporate Governance Code to which members are bound. The UN Global Network also has an active branch in Serbia[145]and the Global Leaders Forum promotes corporate social responsibility in the country.[146] Several laws relating to the protection of the environment include a requirement for companies to report on the environmental consequences of their actions. The Strategy emphasizes that the majority of companies are, however, not quite aware of the importance of reporting on their environmental impact, with the exception of branches of multinational companies and companies with predominantly foreign ownership. Thus, reporting in the area of environmental issues amounts to providing legally required reports and studies to competent institutions and an occasional public announcement on the website of the company, in the media and through PR activities.

In **Spain,** the Royal Legislative Decree 1/2010 (modified in 2014) on Capital Companies only refers to CSR strategy in article 529 ter. as being one of the faculties of the Board of

[140] Minister of Economy, Act of 9 July 2014 on Corporate Social Responsability (Zarządzenie Ministra Gospodarki1 w Sprawie Powołania Zespołu do Spraw Społecznej Odpowiedzialności Przedsiębiorstw)? Poland, 09.07.2014.
www.mg.gov.pl/files/upload/22130/Zarz%C4%85dzenie_DU_MG_Zespol_CSR_21_07_2014.pdf
[141] Corporate Social Responsibility, Poland.
www.csr.gov.pl
[142] The Accounting Act of 29 September 1994 (Ustawa z dnia 29 września 1994 r. o rachunkowości), Poland, 29.09.1994.
http://polishtax.com/wp-content/uploads/2012/01/Polish-Accounting-Act.pdf
[143] Strategy for the Development and Promotion of CSR in the Republic of Serbia for the period 2010 – 2015 (Стратегија Развоја И Промоције Друштвено Одговорног Пословања У Републици Србији За Период Од 2010. До 2015. Године), Sebia, 2010.
http://www.noois.rs/pdf/Strategija_razvoja_i_promocije.pdf
[144] Association of Corporate Directors of Serbia (Удружење корпоративних директора Србије)
http://www.ses.org.rs/eng/ukds.php
[145] The UN Global Compact, The Global Compact Network in Serbia, 06.12.2007.
https://www.unglobalcompact.org/NetworksAroundTheWorld/local_network_sheet/RS.html
[146] The Global Leaders Forum, Serbia.
http://www.csr360gpn.org/partners/profile/business-leaders-forum-serbia/

Directors.[147] Royal Decree 221/2008 created the National Council for Corporate Social Responsibility.[148] The Council's objectives are to:

- provide a forum for discussion on Corporate Social Responsibility among different stakeholders;
- encourage Corporate Social Responsibility initiatives;
- report on initiatives and government regulations affecting the performances of enterprises, organizations and public and private institutions;
- promote standards;
- analyse and report on the development of Corporate Social Responsibility in Spain and abroad;

In compliance with the established objectives, the Council for Corporate Social Responsibility has the following functions:

- to issue reports and conduct studies at government request or on its own initiative.
- to prepare and submit an annual report to the Government
- to constitute an Observatory of Corporate Social Responsibility in Spain.
- to promote and encourage corporate social responsibility initiatives.
- to collaborate and cooperate with other similar councils, including internationally.
- to participate in the way it is determined, in national and international fora set up to address issues of CSR.

In June 2014, a draft for a National Plan on Business and Human Rights was published. It establishes that businesses must avoid that their own activities cause or contribute to cause adverse effects on human rights and tackle such consequences should they occur and prevent or mitigate the negative impact on human rights directly related to operations, products or services by their business relationships, even if they have not helped to generate this negative impacts.[149]

The **Dutch** government policy on CSR, focusing on four action areas which are identified in the renewed EU strategy for CSR (2011-2014) includes the following:

1. alignment of European CSR with global guidelines for CSR by 2014 (OECD Guidelines are considered by the Dutch government as the primary international reference framework)
2. improving disclosure of relevant non-financial information by companies (The Netherlands has implemented Article 46 of the Fourth Accounting Directive requiring legal persons to include information in the annual report on non-financial key performance indicators, to the extent necessary for an understanding of the company's development, performance or position (Article 2:391, paragraph 1 of Book 2 of the Dutch Civil Code). Small and medium-sized companies are exempt from this obligation (Article 396 and 297 of Book 2 of the Dutch Civil Code)
3. market incentives for CSR;

[147] The Royal Legislative Decree 1/2010 (modified in 2014) on Capital Companies (Real Decreto Legislativo 1/2010, de 2 de julio, por el que se aprueba el texto refundido de la Ley de Sociedades de Capital), Spain, 02.07.2010. http://www.boe.es/buscar/act.php?id=BOE-A-2010-10544.

[148] Royal Decree 221/2008 created the National Council for Corporate Social Responsibility (Real Decreto 221/2008, de 15 de febrero, por el que se crea y regula el Consejo Estatal de Responsabilidad Social de las Empresas), Spain,15.02.2008. http://www.boe.es/buscar/act.php?id=BOE-A-2008-3868

[149] National Council for Corporate Social Responsibility, Plan on Business and Human Rights, draft for processing, Spain, 26.06.2014.
http://business-humanrights.org/en/un-guiding-principles/implementation-tools-examples/implementation-by-governments/by-type-of-initiative/national-action-plans

4. enhancing the visibility of CSR and disseminating good practices.

In 2013, the Netherlands presented a National Action plan on business and human rights (Netherlands action plan on business and human rights 2015). The action plan focused on trade, investment and the need for a level playing field. The action plan did not, however, mention research or innovation.

In **France,** CSR laws and regulations in France include:

- • The Law on Employment and Saving Plan of 19 February 2001, which asks fund managers to take into account social, environmental and ethical considerations in the choice of investments.
- • The Law on New Economic Regulations of 15 May 2001, which requires listed companies to introduce environmental and social information within their yearly reports to shareholders.
- • The Law on Retirement Reserve Funds of 17 July 2001, which requires environmental and social information to be introduced in the yearly reports of retirement funds.

In the **United Kingdom**, there is currently no national action plan on CSR. However, there have been calls for one, as recently as 2013 and an official response on 28 March 2014, meant to help guide future government action.[150] It considers, as well, the UK Business and Human Rights Action plan. At present, according to the 2014 Compendium, the government has promoted the application of guidelines found in the UN Global Compact, OECD Guidelines for Multinational Enterprises/OECD Contact Point, and the UN Guiding Principles on Business and Human Rights. Since October 2013, publically listed companies have been legally obliged to report on social and environmental issues, and the "*Environmental Reporting Guidelines* provides businesses with a platform to help identify the environmental issues over which they have influence and the steps they can take to address these."[151]

Other non-legal efforts include the business resource efficiency hub for small and medium enterprises, and voluntary agreements to address cross-sector environmental impacts and supply chains. Further attempts to address responsibility in supply chains are found in the trading for good initiative.

9 RESEARCH INVOLVING HUMANS

9.1 NATIONAL LEVEL

9.1.1 Distinctions in types framework, conceptions of research, compulsory ethics review

The levels and mechanisms used to oversee research involving humans varies throughout the countries included in this report. Most have specific laws regarding human involvement in biomedical trials with some countries even going as far as making explicit

[150] *Corporate Social Responsibility, National Public Policies in the European Union, Compendium 2014*. European Commission, 2014
[151] *Ibid*

distinction between science and biomedical. When national legislation may not address human involvement in research, there are various methods addressing the topic, most often codes of conduct, as well as the general non-legislative, such as institutional, procedures governing ethics assessment of research involving humans. In all countries, the favourable opinion of the competent ethics committee must be received before commencing clinical trials. There are varying degrees of adoption and conformity to EU level regulations, either by updating existing laws or drafting new legislation.

Austria has national legislation concerning human subject research in biomedical research, which is regulated by the University Act, the Hospital Act the Medicinal Products Act[152] and the Act on Medical Devices.[153]

Ethical principles which apply relate to the Regulation on clinical trials on medicinal products for human use (2014/536/EU)[154], the Council Directive concerning medical devices (93/42/EEC);[155] and the Helsinki Declaration, which have been transposed into national legislation if not directly applicable. The Act on Medicinal Products e.g.[156] stipulates that clinical trials shall only be admissible if the risks for the participant in relation to the expected results for medical research are justifiable.[157] Obligatory ethics review is limited to Clinical trials of medicinal products and medical devices, application of new medical methods, applied medical research, non-interventional studies, research in care (experimental and interventional studies) as well as the application of new care concepts and methods (see above). A person chosen as monitor is foreseen in the relevant legislative acts. The monitor is not responsible for safety standards in terms of content, but for overseeing the correct implementation of the research protocol and its implementation.[158] Adverse events have to be reported to the respective authority (Bundesamt für Sicherheit im Gesundheitwesen) by the research sponsor.[159] Sanctions in regard to non-compliance with the ethical prerequisites are embodied in the Medicinal Products Act[160] and the Medical Devices Act. Infringements are classified as administrative offences.[161]

[152] Legislation for drug law, (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 16.03.2015. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441

[153] Legislation for Medical Devices Act (Gesamte Rechtsvorschrift für Medizinproduktegesetz), Austria, 16.03.2015. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003

[154] The process of adaption has started and will be finalised by spring 2016.

[155] The Directive is subject to reform.

[156] Act on Medicinal Products http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441

[157] § 29, Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), "Die klinische Prüfung von Arzneimitteln darf nur durchgeführt werden, wenn die Risken, die mit ihr für den Prüfungsteilnehmer verbunden sind, gemessen an der zu erwartenden Bedeutung des Ergebnisses der Prüfung für die Medizin vertretbar sind (…)". Austria, 13.03.2015 http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441

[158] § 333, 34, Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 13.03.2015. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441

[159] § 41e, Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 13.03.2015. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441

[160] §82b, Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 13.03.2015. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441

[161] Such offences are fined between € 25.000 and € 50.000.

In **Germany** there are no comprehensive statutory regulations governing all research on human beings except within clinical trials.

The statutory requirement of an ethical review is limited to **clinical trials**, and requires a favourable opinion and approval from the competent higher federal authority.[162]

Detailed rules on informed consent apply to **clinical trials, including what constitutes consent and who may give it** (Section 40 (4) 5 and Section 41 (3) 4 of the Act on Medicinal Products). The concepts of presumed or broad consent are not referred to in acts on clinical trials. The research participant can withdraw from clinical trials at any time. Furthermore, the person concerned is to be given the opportunity to have a counselling session with an investigator or a member of the investigating team - a doctor, or in the case of a dental trial, a dentist - about the other conditions surrounding the conduct of the clinical trial. Moreover, prior to the start of the clinical trial, a person concerned should give a written consent that refers specifically to the collection and processing of personal data. (Section 40 subsection 1 sentence 3 letter c).

The obligation that the interests and welfare of the human being participating in research should prevail over the interest of society or science is not explicitly mentioned, however risk is explicitly addressed. According to Section 40 (1) 2, the clinical trial of a medicinal product may only be conducted on human beings if, and as long as, among others, *"the foreseeable risks and inconveniences are medically justifiable, compared with the benefit for the person on whom the clinical trial is to be conducted (person concerned), and the anticipated significance of the medicinal product for medical science"*.

Other conditions that need to be fulfilled are the following:

- a sponsor or a representative of the sponsor whose registered place of business is situated in a Member State of the European Union or in another State Party to the Agreement on the European Economic Area, is available
- the foreseeable risks and inconveniences are medically justifiable, compared with the benefit for the person on whom the clinical trial is to be conducted (person concerned), and the anticipated significance of the medicinal product for medical science,

Moreover, there are specific rules that apply to medicinal products that consist GMO

There are other conditions that relate to the quality of the place where the clinical trial is to be conducted as well as the obligations of the investigator. Treatment without consent is only possible in the case of sick participants: "if, in an emergency situation, consent cannot be obtained, treatment which is necessary without delay to save the life of the person concerned, restore good health or alleviate suffering can be started immediately. Consent for continued participation must be obtained as soon as it is possible and reasonable." (Section 41 subsection 1)
There is no duty of safety monitoring by the ethics commission. There is a requirement to report on adverse effects in the case of clinical trials, which follows from EU law.

[162] Section 40 (1), Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 13.03.2015. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441

In the **Netherlands,** according to the Medical Research Involving Human Subjects Act, medical scientific research is "scientific research that makes human beings subject to intervention or change in practices."[163] However, this definition is subject to interpretation is is currently being revised. Before research with human subjects can commence in the Netherlands the research file must first be approved by an independent committee of experts. This is laid down in the Medical Research Involving Human Subjects Act (WMO) (CCMO 2013) which explicitly outlines which types of research require review,

> "Article 1
> As scientific research for which the research protocol must have obtained a positive judgment of the central committee referred to in Section 14 of the Medical Research Involving Human Subjects Act is specified:
>
> a. scientific research in which the genetic material of human body cells is deliberately modified or its functioning is specifically influenced;
> b. scientific research in which live components of an animal or of a foetus or embryo of an animal, or a human component that has deliberately been brought into contact therewith are introduced in or attached to the body of a human;
> c. scientific research in which products to which Section 2, first clause, or Section 3, first clause, of the Opium Act is applicable are prescribed in pharmaceutical form to people who are addicted to these products, for the treatment of the addiction to those products;
> d. scientific research on gametes;
> e. scientific research aimed at the development of a vaccine;
> f. scientific research focused on the development of cell therapy, using living cells;
> g. scientific research with a medicinal product containing genetically modified organisms as defined in Article 1, first paragraph, section f, of the Genetically Modified Organisms Environmental Conservation Decree."[164]

According to **Spanish** law, biomedical research includes "basic and clinical research, except in the latter case of clinical trials with drugs and medical devices, which are governed by specific regulations."[165]

The law establishes that interest and welfare of humans participating in biomedical research shall prevail over the interest of society or science [166]

The authorization and development of any biomedical research project on humans or biological material (including any procedure that may imply a physical or psychological risk to the subject) requires the prior prescriptive favourable report of the Research Ethics Committee[167]. Any other research involving humans must abide by the Law on Data Protection. In research centres that use personal data, as the law requires informed consent,[168]

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[163] In Dutch: wetenschappelijk onderzoek: medisch-wetenschappelijk onderzoek waarvan deel uitmaakt het onderwerpen van personen aan handelingen of het opleggen aan personen van een bepaalde gedragswijze.
Ministry of Health, Welfare and Sport, Act of 26 February 1998, containing rules on medical research involving human subjects (Medical Research (Human Subjects) Act) (Wet medisch-wetenschappelijk onderzoek met mensen), The Netherlands, 26.02.1998.
http://www.ccmo.nl/en/medical-scientific-research-and-the-wmo

[164] Act of 26 February 1998, containing rules on medical research involving human subjects (Medical Research (Human Subjects) Act) (Wet medisch-wetenschappelijk onderzoek met mensen, WMO),The Netherlands, 26.02.1998.
http://www.ccmo.nl/en/medical-scientific-research-and-the-wmo

[165] Article 1.3., Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007.

[166] Article 2.b)., Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007.

[167] Article 2. e), Law 14/2007, of 13 July 2007 on biomedical research, Spain, 13.07.2007.

[168] Article 6, Law 15/1999 of 13 December on the Protection of Personal Data, Spain, 13.12.1999.

the research projects are assessed by Ethical Committees. Projects that use only aggregated data (in sociological research) do not need previous ethical assessment.

Research involving humans in **Serbia** is governed by several legal acts and they imply only to biomedical research. Major laws and soft laws that regulate area of research involving humans are: *Law on Medicines and Medical Devices* (Official Gazette of the Republic of Serbia no. 30/2010), *Law on Patient Rights* (Official Gazette of the Republic of Serbia no. 45/13). *Rulebook on the Contents of the Application*, *Documentation on the Approval of Clinical Trials for Medicines and Medical Devices, as well as the Method of Implementation for Clinical Trials of Medicines and Medical Devices* (Official Gazette of the RS no. 64/2011). All clinical trials are required to receive a favourable opinion of the competent ethics committee.

9.1.2 Principles: Informed Consent, Risk, Benefits, Safety Monitoring

Austria

Ethical principles which apply relate to the Regulation on clinical trials on medicinal products for human use (2014/536/EU)[169], the Council Directive concerning medical devices (93/42/EEC);[170] and the Helsinki Declaration, which have been transposed into national legislation if not directly applicable The Act on Medicinal Products e.g.[171] stipulates that clinical trials shall only be admissible if the risks for the participant in relation to the expected results for medical research are justifiable.[172] All relevant legislative acts foresee informed written consent from research participants as a precondition for research. The legislation stipulates that participants have to be informed by a medical doctor on the nature, implications, significance, and risks of the clinical trial and the participant has to give written informed consent. The consent can be withdrawn at any time. Information has to be provided orally and in written form. The information has to be clear on the fact, that non-participation does not entail negative consequences in particular for medical treatment. The written informed consent has to be dated. The participants must also be informed of the possible use of personal data and must give respective written consent.[173] The legislative provisions do not foresee consent to be a continuing process. As regards human subject research there is no concept of presumed or broad consent. A monitor is foreseen in the relevant legislative acts.

[169] The process of adaption has started and will be finalised by spring 2016.
[170] The Directive is subject to reform.
European Council, Directive 93/42/EEC of 14 June 1993 concerning medical devices, Brussels, OJ L 169, 12.7.1993.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF
[171] § 29, Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 13.03.2015.
http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441
[172] § 29, Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 13.03.2015.
"Die klinische Prüfung von Arzneimitteln darf nur durchgeführt werden, wenn die Risken, die mit ihr für den Prüfungsteilnehmer verbunden sind, gemessen an der zu erwartenden Bedeutung des Ergebnisses der Prüfung für die Medizin vertretbar sind (…)".
http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441
[173] §38 and 39, Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 13.03.2015.
http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441

The monitor is not responsible for safety standards in terms of content, but oversees the correct implementation of the research protocol and its implementation.[174] Adverse events have to be reported to the respective authority (Bundesamt für Sicherheit im Gesundheitwesen) by the sponsor of the research.[175] Sanctions in regard to non-compliance with the ethical prerequisites are embodied in the Medicinal Products Act[176] and the Medical Devices Act. Infringements are classified as administrative offences.[177]

Germany

Detailed rules on informed consent apply to **clinical trials, including what constitutes consent and who may give it.** (Section 40 (4) 5 and Section 41 (3) 4) The concepts of presumed or broad consent are not referred to in acts on clinical trials. Research participant can withdraw from clinical trials at any time. Furthermore, the person concerned is to be given the opportunity to have a counselling session with an investigator or a member of the investigating team who is a doctor, or in the case of a dental trial, a dentist about the other conditions surrounding the conduct of the clinical trial. Moreover before the start of the clinical trial a person concerned should give a written consent that refers specifically to the collection and processing of personal data. (Section 40 subsection 1 sentence 3 letter c).

Risk is explicitly addressed. According to Section 40 (1) 2 the clinical trial of a medicinal product may only be conducted on human beings if and as long as, among other, *"the foreseeable risks and inconveniences are medically justifiable, compared with the benefit for the person on whom the clinical trial is to be conducted (person concerned), and the anticipated significance of the medicinal product for medical science"*.

Other conditions that need to be fulfilled are the following:

- a sponsor or a representative of the sponsor whose registered place of business is situated in a Member State of the European Union or in another State Party to the Agreement on the European Economic Area, is available
- the foreseeable risks and inconveniences are medically justifiable, compared with the benefit for the person on whom the clinical trial is to be conducted (person concerned), and the anticipated significance of the medicinal product for medical science,

There are other conditions that relate to the quality of the place where the clinical trial is to be conducted as well as the obligations of the investigator. Treatment without consent is only possible in the case of sick participants: "if, in an emergency situation, consent cannot be obtained, treatment which is necessary without delay to save the life of the person concerned, restore good health or alleviate suffering can be started immediately. Consent for continued participation must be obtained as soon as it is possible and reasonable." (Section 41 subsection 1)
There is no duty of safety monitoring by the ethics commission. There is the requirement to report on adverse effects in the case of clinical trials, which follows from the EU law.

[174] § 333, 34, Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 13.03.2015. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441
[175] § 41e, Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 13.03.2015. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441.
[176] §82b. Act on Medicinal Products (Gesamte Rechtsvorschrift für Arzneimittelgesetz), Austria, 13.03.2015. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441
[177] Such offences are fined between € 25.000 and € 50.000.

Netherlands

The VUMC/AMC code of conduct[178] is exemplary on the requirements for research involving humans:

> In any type of scientific research, an absolute prerequisite is to respect the participants and their rights. In medical research, this prerequisite is fundamental. It is also enshrined in the law in various ways; for example the rights that research subjects have to protect their physical and mental integrity and their privacy are laid down in law. Lastly, respect for subjects involved in research is essential if the trust and cooperation of potential participants is to be secured for the future.
>
> Respect for the persons or participants cannot be fully captured in rules or procedures. This means that respect for participants is not only a matter of obeying rules and following verification procedures: it is also a state of mind. Researchers need to be open to and feel responsible for those interests of participants that could be affected by the research, and to ensure that the participants are aware of this (AMC/VUMC, 2014).

All university hospitals and several other hospitals and institutes in the Netherlands have their own MEC/MREC. Most of the criteria used by the committee are laid down in international documents, for example the Declaration of Helsinki (revised in Seoul in October 2008) and the Good Clinical Practice guidelines (which are applicable to interventional clinical research with medicinal products in the EU, the USA and Japan). In essence, the legal requirements are as follows:

- The research must be worthwhile and should lead to medical progress as regards the question it sets out to answer, be sound as regards design and execution, and be reasonable, that is, its value must be in proportion to the burden on and the risks to the subjects;
- The subjects (or their legally acceptable representatives) must have been properly informed in writing and have given their written consent. The information provided must include the purpose, nature and duration of the research and the risks and problems it could entail for subjects;
- The subjects must be adequately insured (specific WMO insurance);
- More stringent requirements apply in the case of minors, incompetent adults and subjects who are dependent in some other way(AMC/VUMC 2014).

> On 1 March 2006, the WMO law was changed, implementing the international Good Clinical Practice guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This implies that clinical research with either registered or nonregistered medicinal products must be conducted in compliance with these guidelines. Other research that is not subject to the WMO should preferably also be conducted in the spirit of the ICH Good Clinical Practice guideline. This is not a regulatory requirement, but a common sense approach (AMC/VUMC, 2014).

[178] AMC and VUMC. (2014). *Research Code, Scientific integrity at VUmc and AMC*. Opgehaald van AMC Research Code: https://www.amc.nl/web/AMC-website/Research-Code/3-Respect-for-human-subjects.htm

> For research that is not subject to the WMO, less stringent requirements apply: in principle oral informed consent written down in the file of the patients adequate and there is no need for specific insurance (AMV/VUMC, 2014).
>
> The Medical Research Involving Human Subjects Act (WMO) covers medical scientific research in which people are subjected to interventions or have to follow established behavioural rules. The main purpose of the act is to protect research subjects (patients and healthy volunteers) against the risks and burdens of biomedical research involving human subjects without unnecessarily hampering the progress of medical–scientific research. (AMC and VUMC 2014).[179]

The principle of informed consent (Health Council, 2005) means that the care provider may only conduct research or administer a treatment if the patient or client (or his/her representative) has given his/her consent based on prior information. This principle is rooted in highly complex ethical and legal considerations and has been enshrined in the so-called 'Medical Treatment Agreement Act' (WGBO). It can be broken down into various component parts: the actual provision of information; the comprehension of the information; the voluntariness of the choice; and the consent itself.

Poland

The Act on Medical Profession stipulates that medical experiment can be performed when the anticipated therapeutic or scientific or cognitive benefits are considerable, and the anticipated achievement of the benefits, as well as the expediency and the way the experiment is executed are justified in the light of the contemporary knowledge and are consistent with the principles of medical ethics.

The explicit obligation that the "rights, safety and well-being of the trials subject shall prevail over the interests of science and society" is included in the Pharmaceutical Law which contains rules on clinical trials.

The concrete rules on informed consent apply to medical experiments. At the same time, according to the Polish Constitution "[n]o one shall be subjected to scientific experimentation, including medical experimentation, without his voluntary consent", which would imply that voluntary consent is required in the case of all types of research.

According to the Pharmaceutical Law before a clinical trial is conducted, the participant should be informed about the goals, risks and nuisances linked to the clinical trial as well as the conditions how it will be conducted and the right to withdraw from the trial the participant should be informed about the

There is no requirement for consent to be a continuing process; at the same time participants can always change their mind and resign from the trial at each stage of the clinical trial (Article 27 of the Act on Medical Profession). The concept of presumed or broad consent is not referred to in any laws. There are also no rules on future uses of data or samples.

In the case of patients unable to give consent, either due to the lack of legal capacity or the state they are in, the consent has to be obtained from their legal representative or the court.

[179] AMC and VUMC. (2014). *Research Code, Scientific integrity at VUmc and AMC*. Opgehaald van AMC Research Code: https://www.amc.nl/web/AMC-website/Research-Code/5-Methods-Good-practice.htm?tab=533560

The decision of the legal representative (e.g. a parent) can be overridden by the decision of the court, if the physician believes it goes against the interest of the patient. Moreover a decision of the legal representative that goes against the interest of the patients may give rise to criminal sanctions.[180]

In Article 37e of Pharmaceutical law it is stipulated that financial incentives cannot be offered to sick participants, as well as minors. They can only receive a compensation of costs.

Specific rules on research on minors concern medical experiments and clinical trials. There are no statutory rules on other types of research.

Medical experiments: The consent of the child is required if the child is able to make a properly informed decision (Article 25 point 2). In emergency cases when the life of the participant is threatened consent does not have to be obtained (Article 25 point 6). The participation of a minor in non-therapeutic research is possible, if the anticipated benefits have direct importance for the minor's health and the risk is small. Scientific experiments involving the participation of a minor is not permissible where there is the possibility of conducting such experiments with comparable effects with the participation of an individual with full legal capacity (Article 25 point 3).

Clinical trials: The rules on the participation of minors in clinical trials included in Pharmaceutical law replicate the relevant provisions of EU directives.
ß
The rules on safety monitoring concern clinical trials and in that respect they implement the EU directives. There are no statutory provisions that would apply to different types of research. There are no laws or guidelines on safety monitoring that concern other type of human subject research.

Serbia

There is an explicit obligation that the interests and welfare of the human being participating in research should prevail over the interest of society or science (principle of human primacy). Article 60 of *Law on Medicines and Medical Devices* emphasizes subject's protection in clinical trials: subject's rights, safety and interests must be prioritized in relation to the interests of science and society as a whole. Ethical review is required only for biomedical research and clinical trials as well as an informed consent of the participants. Information that should be provided to research subjects are specified in article 11 of *the Rulebook on Clinical Trials of Medicines*. Before the start of clinical trials the principal investigator or team member is required to acquaint the subjects both in writing and orally with: 1. the objective and procedure of the clinical trial of the drug; 2. the expected positive and negative effects of the clinical trial; 3 possible inconveniences, effects and risks of the clinical trial; 4 other treatment options without the use of the drug which is tested; 5 the procedure for ensuring confidentiality of personal data in the course of clinical trials, 6 possible abandonment, or interruption of the clinical trial at the request of the subject, at any time, or by withdrawing given written consent for participation in the clinical trial of the drug. Member of research team is obligated to provide the research subject with information.

[180] For more information: http://www.centrumratownictwa.com/zgoda-zastepcza-w-medycynie-i-pierwszej-pomocy.html

There is no requirement for consent to be a continuing process. Concept of presumed or broad consent is not defined. Informed consent standards mentioned before pertain specifically to individual consent. The law makes it explicit that the research participant can withdraw from the research at any time and that there is a need to balance risk and benefits. This matter is addressed in article 61 of *Law on Medicines and Medical Devices* which states that clinical trial can be conducted if medicinal product use of a medicinal product under the trial is greater than its possible risks to life and health of subjects. There is no legal ban on possible compensation of research participants.

Report on adverse effects during clinical trial and research is mandatory. Article 87 of *Law on Medicines and Medical Devices* states that If serious and unexpected adverse reactions or serious adverse events during the conduction of a clinical trial occur, a sponsor has to notify the Agency (Medicines and Medical Devices Agency of Serbia) immediately as well as Ethics Committee of a legal entity in which the clinical trial is being conducted.

Control over the conduction of clinical trials is responsibility of the Agency, as stated in article 88 the Agency performs control over the conduction of clinical trials.

Spain

The law establishes that interest and welfare of humans participating in biomedical research shall prevail over the interest of society or science [181] To respect the freedom of participants in a research project it is necessary to obtain their previous express and written consent[182]. The law is comprehensive to include what types of information are required to be given to the participant, the means of doing so, methods of applicable compensation, and how the information may be used for the purposes of the study and in the future. (Law on Biomedical Research, Article 15)

Law does not allow broad or presumed consent. The Law on Biomedical Research establishes that the carrying out of research on a person shall require the "express, specific and written consent of the person", although it allows the possibility of consent through a legal representative in the case of minors or disabled persons (see below). [183]

The law also specifies that:

- the research participant can withdraw from the research at any time
- there is a need to balance risk and benefits. Evaluating the balance of risks and anticipated benefits arising from the study is one of the functions of the RECs. In invasive procedures (with the potential of psychical risks): Research shall not involve risks to humans and disproportionate inconvenience regarding the potential benefits that can be obtained.

[181] Article 2.b), Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007. http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf

[182] Article 4: "The free will of persons that may participate in biomedical research or that could provide their biological samples shall be respected. Their previous express and written consent must be provided once the adequate information has been provided". Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007. http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf

[183] Article 13, Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007. http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf

According to law, the donation of tissue is gratuitous[184], but the donor of the sample can be compensated for the physical discomforts, expenses and other inconveniences that may be derived from the taking of the sample[185].

The Royal Decree on clinical trials establishes the obligation of the researcher to inform the promoter of the trial of any adverse effects during clinical trials. The promoter must maintain a register of adverse effects and inform the Spanish Agency of Medicaments and Health Products, the regional authorities and the REC.[186]

In **France**, There is a legal requirement to obtain an informed consent from research participants in the case of biomedical research. An entire chapter of the Public Health Code (PHC) is devoted to information of the person who lends her/himself to biomedical research and to the collection of her/his consent (Articles L1122-1 to 2 of the PHC). According to Article L1122-1-1 of the PHC, no biomedical research may be carried on a person without her/his free and informed consent.

There is no legal requirement to obtain an informed consent from research participants in the case of non-interventional research. However, there are additional provisions for research on Biological Collections and research on personal data (including clinical and genetic data) (non-opposition of the person following the information procedure).

Article L1121-2 of the PHC introduces the notion of risk and benefits balance stating that a biomedical research can only be carried out if the foreseeable risk to research participant is in proportion to the expected benefit for her/him or to the interest of this research.

Articles R1123-38 to 55 of the PHC address the question of vigilance and urgent safety measures in biomedical research.

Especially, according to the Article R1123-38 of the PHC, for biomedical research on drugs, the General Director of the French National Agency for Medicines and Health Products Safety (*Agence française de sécurité sanitaire des produits de santé* or ANSM) ensures that all suspicions of serious unexpected adverse reactions that occurred in France and brought to its attention are recorded and entered in the European database set up by the European Medicines Agency.

For research on routine care only an absence of opposition of the person concerned following the information procedure is required. Indeed, research projects on routine care are part of the normal care process of a patient. Hence, they are covered by provision on consent to normal care process.

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[184] Article 7: "The donation and use of human biological samples shall be gratuitous, whichever its specific origin, and the compensations that are provided for in this Law can in no way entail a lucrative or commercial nature", Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007.
http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf

[185] Article 58: "an economic compensation may be established for the physical discomforts, expenses and other inconveniences that may be derived from the taking of the sample". Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007.
http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf

[186] Article 42-47, Royal Decree 223/2004 of 6 February 2004 for which clinical trials with medication are regulated, Spain, 06.02.2004.
http://www.boe.es/buscar/doc.php?id=BOE-A-2004-2316

10 PRIVACY AND DATA PROTECTION IN THE FIELD OF RESEARCH AND INNOVATION

10.1 EU

The most comprehensive regulation involving data protection on the EU level is the Data Protection Directive (95/46/EC). It is described in *Biobanks for Europe*[187]*:*

"The other regulatory model that has been relied upon in the European legal system is the Data Protection Directive (95/46/EC). This stipulates the principles that must apply to the protection of personal data within the Europe. Given the processing of personal data in biobanks-based research, which can involve sensitive data, such as health and genetic information, socio-demographic data, life style and behavioural data, the requirements found in the Directive have been important for biobanks. As well as providing the principles for fair processing, the Directive also stipulates that data protection supervisory authorities should provide oversight and supervisory roles. This model is now mirrored, at the highest level, in the EU sources, within Art. 8 of the Charter of Fundamental Rights of the European Union and Art. 16 Treaty on the Functioning of the European Union (TFEU), provision applicable to all the matters falling under EU competence. Following the solution adopted by the Council of Europe Convention of 28 January 1981, No. 108 (Article 6), the Directive 95/46/EC also allows the use of personal data (sensitive data included) for research purposes, providing Member States adopt "suitable safeguards". This is a wide discretion. In particular, some provisions contained in the Directive allow enough flexibility to allow the processing of personal data for secondary historical, statistical or scientific research purposes, as long as there are appropriate safeguards in place. This means that in the case of research, there are exemptions from two of the fair processing principles. Under this exemption, data can be kept for a longer than the original purpose and if the provision of information about secondary research purposes proves impossible, or would involve a disproportionate effort, or if recording or disclosure is expressly laid down by law, then information about the processing does not need to be given to research participants.

Accordingly, the above provisions – whose purpose was to ensure sufficient flexibility and to reconcile data protection principles and research needs – have less a considerable margin of maneuver to Member States. This discretion allows them to determine (via domestic legislation) if, and how, to strike a satisfactory balance between protecting basic values of individuals and safeguarding medical and scientific research along with public health goals.
In the case of biobank-based research, it should be highlighted that the data protection regulatory model with its major principles (e.g. fairness, lawfulness, transparency, finality, necessity, security, etc.) must be applied not only to the processing of personal data, but also – albeit with some ambiguities – to the biological samples used for research purposes (so far they can be referred directly or indirectly to the participant). In biobank research it is not the tangible features of biological samples that are at issue but the informational content. It is therefore the information derived from biological samples rather than the biological sample as such that really matters in a biobank-based research. It might be argued that the biological sample (in its physical dimension) plays basically an ancillary role – being the container or vehicle of the information at issue. This is the stance taken by the Article 29 Working Party in its "Working Document on Genetic Data" adopted on 17 March 2004 (WP91) as well as by some European data protection authorities.

This is in line with the European Court of Human Rights' decisions and the Council of

[187] [187] European Commission, Biobanks For Europe, Brussels, 2012.
http://www.coe.int/t/dg3/healthbioethic/Activities/10_Biobanks/biobanks_for_Europe.pdf

Europe's Recommendations on the use of analysis of deoxyribonucleic acid (DNA) within the framework of the criminal justice system (Principles 7 and 8); and R (92) 3 on Genetic Testing and Screening for Health Care Purposes (Principle 8a). The same views would appear to underlie the decisions by the European Court of Human Rights in S. and Marper v. UK and in Van Der Velden v. The Netherlands. In the Marper case the Court said that "namely fingerprints, DNA profiles and cellular samples, constitute personal data within the meaning of the Data Protection Convention as they relate to identified or identifiable individuals".
This means that the principles applying to the retention and circulation of biological samples should not differ significantly from personal data protection principles even if the legal framework devised for personal data were not found to be directly applicable."

10.2 NATIONAL LEVEL

In **Austria,** the respective rules regarding scientific research are laid down in the Act on data protection[188]. The following data may be used for scientific research:

- Data which is publicly available,
- Data which were established for other research or other purposes in a legitimate manner,
- Data which is only indirectly personalised.

Other data may only be used for research purposes with consent of the data subject or with the approval of the data protection authority. The data authority can give approval

- if obtaining of consent is impossible, as the data subject cannot be contacted or contacting the data subject is disproportionate,
- if there is public interest in the use of the data,
- if the controller has the necessary professional qualification.

Sensitive data (in particular health data) may only be used after approval by the data protection authority if there is an important public interest, or if the controller can guarantee confidential data processing.

In **Germany,** the rules on the processing of personal data for research purposes are laid down in the Federal Data Protection Act[189]. Under Section 14, storage, modification or use of personal data obtained for other purpose may be admissible if this is necessary in order to conduct scientific research. In such a case, scientific interest should substantially outweigh the interest of the data subject, and the research purpose cannot be attained by other means or could be attained only with disproportionate effort. If personal data is collected or stored for scientific research purposes, it may be processed or used only for such purposes. Personal data shall be rendered anonymous as soon as the research purpose permits this. Until such time as the data is anonymised, the characteristics enabling information concerning personal or material circumstances to be attributed to an identified or identifiable individual shall be stored separately. They may be combined with the information only to the extent required by

[188] § 46 a, Act on Data Protection, Austria, 2000.
http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=Bundesnormen&Dokumentnummer=NOR40150430&ResultFunctionToken=75e29e34-502f-4742-b1b7-b498b00abbb3&Position=1&Kundmachungsorgan=&Index=&Titel=&Gesetzesnummer=&VonArtikel=&BisArtikel=&VonParagraf=&BisParagraf=&VonAnlage=&BisAnlage=&Typ=&Kundmachungsnummer=&Unterzeichnungsdatum=&FassungVom=09.12.2014&VonInkrafttretedatum=&BisInkrafttretedatum=&VonAusserkrafttretedatum=&BisAusserkrafttretedatum=&NormabschnittnummerKombination=Und&ImRisSeit=Undefined&ResultPageSize=100&Suchworte=Datenschutz

[189] Act on Data Protection (Bundesdatenschutzgesetz), Germany, 20.12.1990.
English: http://www.gesetze-im-internet.de/englisch_bdsg/federal_data_protection_act.pdf
German: http://www.gesetze-im-internet.de/bundesrecht/bdsg_1990/gesamt.pdf

the research purpose. Bodies conducting scientific research may publish personal data only if the data subject has consented or this is indispensable for the presentation of research findings. Consent should be free and informed. In general, it should be given in writing.

In **Poland,** the rules on the processing of personal data for research purposes are laid down in the Act of 29 August 1997 on the Protection of Personal Data[190]. According to Article 26.2.1, the processing of data, for a purpose other than that intended at the time of data collection is allowed provided that it does not violate the rights and freedoms of the data subject and is done for the purposes of scientific, didactic, historical or statistical research. As regards sensitive data (including medical records), their processing is, as a general rule, prohibited (Article 27.1). However, research enjoys an exemption – processing of this type of data is possible if it is necessary to conduct scientific research including preparation of a thesis required for graduating from university or receiving a degree. Results of scientific researchers shall not be published in a way which allows identifying data subjects. Researcher who processes personal data should protect the interests of data subjects with due care. In general, data processors are obliged to notify the data subject about the processing and provide him or her with information. However, researchers as data processors enjoy certain benefits in that respect: for those cases where data processing is for scientific, didactic, historical, statistical or archival purposes, the controller may not have to notify the data subject about the processing of his/her personal data, if the provision of such information involves disproportionate efforts. If the researcher obtains data from a third party, he or she is not obliged to obtain the consent of the subject if the data are necessary for research, the processing does not violate the rights or freedoms of the data subject and the obtaining of consent would involve disproportionate efforts or endanger the success of the research.

In **Serbia,** the Law on Scientific and Research Activities in Article 66 stipulates that, in cases of the use of personal data the provisions of the law governing the protection of personal data are applied, unless this law provides otherwise. The waw on personal data protection[191] in Article 10 emphasises that consent to data processing is deemed to be valid if given by a person who has received prior information from the collector of the data. When it comes to processing data for historical, statistical or research, however, the same legal acts states that data collected and processed for other purposes can be processed for historical, statistical or research and development purposes, provided they are not used in decision-making or in the taking of measures against the person concerned and only if adequate safeguards are in place. The Law also states that measures for protecting for data archived solely for historical, statistical or science and research purposes shall be governed by a separate regulation, until this day this regulation are not created. Article 23 of this Law also states that, if personal data are used solely for research and development purposes and statistical purposes, for as long as such usage of data continues, the right to notification, access and copy may be restricted.

In **Spain, Article 5 in** the Law on Biomedical Research establishes the need to guarantee the privacy and confidential treatment of personal data, in accordance with Law 15/1999 on the

[190] Act on the Protection of Personal Data of of 29 August 1997 (Ustawa z dnia 29 sierpnia 1997 r. o ochronie danych osobowych), Poland, 29.08.1997.
http://isip.sejm.gov.pl/DetailsServlet?id=WDU19971330883

[191] Law on personal data protection of 4 November 2008 (Zakon o zaštiti podataka o ličnosti), Official Gazette of Republic of Serbia no. 97/2008, 104/2009, 68/2012, and 107/2012 www.legislationline.org/download/action/download/id/5485/file/Serbia_law_personal_data_protection_EN.pdf

protection of Data of a Personal Nature[192]. In general, personal data may not be used for purposes incompatible with those for which they were collected. Processing of personal data for historical, statistical or scientific purposes is, however, not considered incompatible (Article 4.2 of the Law 15/1999). Where the personal data have not been obtained from the data subject, he or she should be provided with a set of information. This obligation may be not imposed in the case of processing for historical, statistical or scientific purposes (Article 5.4 of the Law 15/1999). Personal data may exceptionally be kept longer than necessary for the purposes for which they were obtained or recorded in a form that permits identification of the subject, if it has a historical, statistical or scientific value (Article 4.5 of the Law 15/1999). According to Law 14/2007 on Biomedical Research, the same guarantees as in the case of personal data that are the result of the biomedical research shall be applicable to biological samples that are the source of information of a personal nature (Article 5). The disclosure of data of a personal nature to third parties outside of the medical-assistance or to biomedical research shall require the express and written consent of the interested party. In the event that the data obtained from the subject source could reveal information of a personal nature about his or her family members, its transmission to third parties shall require the express and written consent of all those concerned. The use of data related to the health of persons with purposes different to those for which the consent was given shall be forbidden. Any person who has access to data of a personal nature, in the duty of their functions concerning the provisoin of a medical health care service or biomedical research, irrespective of the reach of either, shall be subject to a duty of secrecy. If the publication of the results of a research is not possible without identifying the person who participated or who provided biological samples, these results shall only be published when there has been a previous and express consent of this person.[193] The obligations of personal data controllers and safeguards are specified in Royal Decree 1720/2007. The subjects maintain the right to access, rectify, cancel and oppose the processing of data at any time. The regulation on the protection of Data of a Personal Nature requires the maximum level of protection for personal health data[194].

In **the Netherlands,** the general rules on the processing of personal data are laid down in the Data Protection Act[195]. The processing of personal data is possible in specific cases (Article 8). Processing of data collected with a different aim is, however, possible for scientific purposes (Articles 9 and 10.2). Moreover if the processing is carried out by institutions or services for the purpose of scientific research or statistics, and necessary arrangements have been made to ensure that the personal data can only be used for statistical or scientific purposes, the obligations towards data subject are limited (Article 44). Finally, the prohibition on the processing of sensitive personal data (e.g. concerning someone's health) for the purpose of scientific research or statistics does not apply where:

- the research serves a public interest
- the processing is necessary for the research or statistic concerned
- it appears to be impossible or would involve a disproportionate effort to ask for express consent, and

[192] Organic Law 15/1999 of 13 December 1999 on Personal Data Protection, Spain, 13.12.1999. www.boe.es/buscar/act.php?id=BOE-A-1999-23750

[193] Article 5, Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007. http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf

[194] Royal Decree 1720/2007 of 21 December 2007 on Data Protection, Spain, BOE 19.01.2008. www.boe.es/buscar/doc.php?id=BOE-A-2008-979).

[195] Data Protection Act 2000 (Wet bescherming persoonsgegevens) of 23 November 1999, The Netherlands. http://wetten.overheid.nl/BWBR0011468/geldigheidsdatum_04-02-2015, unofficial translation available at www.coe.int/t/dghl/standardsetting/dataprotection/national%20laws/NL_DP_LAW.pdf

- sufficient guarantees are provided to ensure that the processing does not adversely affect the individual privacy of the data subject to a disproportionate extent.

Guidelines on handling personal data in the case of medical research are (in line with the Data Protection Act and the Law for the Agreement on Medical Treatment) laid down in the Code of Conduct for Medical Research of the Council of the Federation of Medical Scientific Societies[196]. According to the general principle, medical research using personal data may only be conducted with the consent of the subject. The Code envisages however certain exceptions.

In **France** the Data Protection Act (Loi n°78-17 of January 6, 1978 relative à l'informatique, aux fichiers et aux libertés, as revised since) is extremely protective of personal data with stronger protection for what is called sensitive data (données sensibles) which includes information on health. The Act was adopted prior to the first European directive on the protection of personal data. It has been revised since and is considered one of the most protective systems in Europe.

The first Article of the Data Protection Act establishes a connection between privacy and fundamental rights and freedoms and can refer to other protections provided by law (for example, medical confidentiality), which also involve the same guarantees.

Article 6 of the Data Protection Act explicitly outlines that personal data may only be processed if the following conditions are met:
"1° the data shall be obtained and processed fairly and lawfully;
2° the data shall be obtained for specified, explicit and legitimate purposes, and shall not subsequently be processed in a manner that is incompatible with those purposes. However, further data processing for statistical, scientific and historical purposes shall be considered compatible with the initial purposes of the data collection, if it is carried out in conformity with the principles and procedures provided for in this Chapter, in Chapter IV (formalities prior to commencing data processing) and in Section 1 of Chapter V (obligations incumbent upon the data controllers and the rights of individuals) as well as in Chapters IX (processing of personal data for the purpose of **medical research**) and X (processing of personal medical data for the purposes of evaluation or analysis of care and prevention practices or activities) and if it is not used to take decisions with respect to the data subjects;
3° they shall be adequate, relevant and not excessive in relation to the purposes for which they are obtained and their further processing;
4° they shall be accurate, complete and, where necessary, kept up-to-date. Appropriate steps shall be taken in order to delete and rectify data that are inaccurate and incomplete with regard to the purposes for which they are obtained and processed;
5° they shall be stored in a form that allows the identification of the data subjects for a period no longer than is necessary for the purposes for which they are obtained and processed."

According to Article 7:
"Processing of personal data must have received the consent of the data subject or must meet one of the following conditions:
1° compliance with any legal obligation to which the data controller is subject;
2° the protection of the data subject's life;

[196] Council of the Federation of Medical Scientific Societies, the Code of Conduct for Medical Research (Dutch Gedragscodes) 2011, The Netherlands.
http://www.federa.org/sites/default/files/bijlagen/coreon/code_of_conduct_for_medical_research_1.pdf

3° the performance of a public service mission entrusted to the data controller or the data recipient;
4° the performance of either a contract to which the data subject is a party or steps taken at the request of the data subject prior to entering into a contract;
5° the pursuit of the data controller's or the data recipient's legitimate interest, provided this is not incompatible with the interests or the fundamental rights and liberties of the data subject."

According to Article 8:
"I. – **The collection and processing of personal data that reveals, directly or indirectly, the racial and ethnic origins, the political, philosophical, religious opinions or trade union affiliation of persons, or which concern their health or sexual life, is prohibited**.
II. – In so far as the purpose of the processing may so require in respect of certain categories of data, **the prohibition provided for in Section I shall not apply to**:
1° processing for which the data subject has given his express consent, except in cases where the law stipulates that the prohibition provided for in Section I may not be lifted by the consent of the data subject;
2° processing necessary for the protection of human life, but to which the data subject is unable to give his consent because of a legal incapacity or physical impossibility;
3° processing carried out by an association or any other not- profit-seeking religious, philosophical, political or trade union body:
- only for the data referred to in Section I corresponding to the object of that association or body;
- if it relates only to members of this association or body and, when appropriate, individuals who have regular contact with it in connection with its activity;
- and that it relates only to data not transmitted to third parties, except where the data subjects expressly consent to such transmission.
4° processing that relates to personal data that the data subject has made public;
5° processing that is necessary for the establishment, exercise or defence of a legal claim;
6° processing that is necessary for the purposes of preventive medicine, medical diagnosis, provision of healthcare or treatment, or for the management of healthcare services and carried out by a member of a medical profession, or by any other person who, due to his functions, is bound by a duty of confidentiality as stipulated in Article 226-13 of the Criminal Code;
7° statistical processing carried out by the National Institute of Statistics and Economic Studies (INSEE) or one of the statistical services of Ministries in conformity with Act No. 51-711 of 7 June 1951 relating to obligations, co-ordination and confidentiality as regards statistics, following an opinion of the National Council for Statistical Information (CNIS) and in accordance with the conditions provided for in Article 25 of this Act (authorisation by the CNIL);
8° **processing necessary for medical research according to the conditions provided for in Chapter IX (processing of personal data for the purpose of medical research)**.
III. – If the personal data mentioned in Section I are, within a short period of time, to be subject to an anonymisation procedure which the CNIL has earlier approved as complying with the provisions of this Act, the Commission may authorise certain categories of processing according to the conditions stipulated in Article 25 (authorisation by the CNIL), taking their purpose into consideration. The provisions of Chapter IX (processing of personal data for the purpose of medical research) and Chapter X (processing of personal medical data for the purposes of evaluation or analysis of care and prevention practices or activities) shall not apply.
IV. - Likewise, an automatic or non-automatic processing shall not be subject to the prohibition provided for in Section I when it is justified by the public interest and authorised

within the conditions stipulated in Section I of Article 25 (authorisation by the CNIL) or in Section II of Article 26 (authorisation by a decree in Conseil d'Etat after a reasoned and published opinion of the CNIL)."

11 RESEARCH INVOLVING ANIMALS

11.1 EU

The key provision of primary EU legislation that concerns animal welfare is Article 13 of Treaty on the Functioning of the European Union (TFUE) according to which "[i]n formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage."[197]

As regards secondary legislation, the key act is Directive 2010/63/EU revising Directive 86/609/EEC **on the protection of animals used for scientific purposes**[198] adopted on 22 September 2010.

The Directive applies to the so-called "procedures" which refers to "any use, invasive or non-invasive, of an animal for experimental or other scientific purpose, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice" (Article 3 point 1). Procedures may be carried out for a defined set of purposes, listed in Article 5.

The Directive is based on the principle of the Three Rs, to replace, reduce and refine the use of animals used for scientific purposes, e.g. it obliges Member States to ensure that a procedure is not carried out if another method or testing strategy for obtaining the results sought, not entailing the use of a live animal, is recognized under the legislation of the EU (Article 13).

The scope includes foetuses of mammalian species in their last trimester of development and cephalopods, as well as animals used for the purposes of basic research, higher education and training.
All procedures should be classified on the basis of their severity. Member States should ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated (Article 15).

As regards ethical review, the Directive obliges Members States to ensure that projects are not carried out without prior authorization from the competent authority, and that projects are carried out in accordance with authorization, or in the case when a simplified administrative procedure is permitted, in accordance with the application sent to the competent authority or

[197] Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union 2012/C 326/01, Brussels, OJ C 326, 26.10.2012.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT
[198] European Parliament and the Council, Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes, Brussels, 22.09.2010.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063

any decision taken by the competent authority (Articles 36 and 42). Simplified administrative procedures may be introduced for projects containing procedures classified as less severe, unless they use non –human primates (Article 42). According According to recital 39 "(…) an impartial project evaluation independent of those involved in the study should be carried out as part of the authorization process of project involving the use of live animals. Effective implementation of a project evaluation should also allow for an appropriate assessment of the use of any new scientific experimental technique as they emerge."

A report by the EC working group published in 2013 highlighted the importance of "correct, complete, current and relevant provision of information which can be facilitated by well-designed templates accompanied by appropriate guidance. Training of all involved in these processes is crucial."[199] The above-mentioned report lists, among others, principles for an effective project evaluation process including: 1. Availability of suitable scientific and technical expertise – including access to experts in less common areas of science 2. Impartiality – lack of conflict of interests; 3. Proportionality; 4. Consistency; 5. Efficiency; 6. Transparency of the process 7. Access to an independent appeals process; 8. Detailed understanding of the context of and criteria for project evaluation, in particular harm – benefit analysis; 9. Sufficient resources; 10. Knowledge of local culture and practices in establishment(s) where work is carried out.

An application for project evaluation should be submitted by the user of the person responsible for the project. The application should include at least the following elements: the project proposal, a non-technical summary as well as a number of other elements e.g. on the relevance and justification of the use of animals, application of methods to replace, reduce and refine the use of animals in procedures (Article 37, all elements are listed in Annex VI). Both scientific and ethical aspects of projects should be subject to evaluation, e.g. compliance with the requirement of replacement, reduction and refinement (Article 41).

Authorisation may be withdrawn if the project is not carried out in accordance with the project authorization. The withdrawal may not be adversely affected by withdrawal of the authorization (Article 44).

11.2 NATIONAL LEVEL

Animal welfare is not a constitutional goal in all member states. In **Austria,** animal protection has been included among constitutional goals in 2013.[200] According to Article 20a of the **German** Basic Law: "[m]indful also of its responsibility toward future generations, the state shall protect the natural bases of life and the animals by legislation and, in accordance with law and justice, by executive and judicial action, all within the framework of the constitutional order." This provision came into force in 2002. The **United Kingdom** updated its laws regarding domestic animals with the comprehensive Animal Welfare Act of 2006, building on a legal precedent dating back to the Cruelty to Animals Act of 1876.

[199] National Competent Authorities, implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes, Working document on Project Evaluation and Retrospective Assessment, Brussels, 18-19.09.2013. http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_PE-RA.pdf

[200] Federal Constitutional Law on sustainability , animal welfare , the overall environment protection , ensuring the water and food supply and research of 11 July 2013(Bundesverfassungsgesetz über die Nachhaltigkeit, den Tierschutz, den umfassenden Umweltschutz, die Sicherstellung der Wasser- und Lebensmittelversorgung und die Forschung), Germany, 11.07.2013.
http://www.ris.bka.gv.at/Dokumente/BgblAuth/BGBLA_2013_I_111/BGBLA_2013_I_111.html

[In **France**, animal welfare has not been included as a constitutional goal. However, there has been recent deliberation in the French Parliament concerning the normative status of animals. It was finally voted that animals are living beings endowed with sensitivity. The Charter on the Environment refers to "all biological diversity" but has no explicit mention of animals, in particular.]

Animals are mentioned in one paragraph of Article 97 of the **Serbian** Constitution which states that the Republic of Serbia shall organize and provide for, sustainable development; system of protection and improvement of environment; as well as the protection and improvement of fauna and flora.

In **Poland, Spain,** and **the Netherlands,** animal welfare is not set as a constitutional goal. Respective constitutions stipulate the obligation to preserve the environment, without a direct reference to animals.

With regard to animal experimentation, the shape of provisions that are in force in individual states is, to a large extent, a result of the implementation of EU directives. The laws rely on Three Rs principles (reduce, replace, refine) enshrined in the directive referred to above as well as acts of international law (for example the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes CETS No.: 123 ratified by the European Union in 1998.) In terms of the procedural requirements, in order to carry out research, the project has to obtain approval of a competent authority.

In Austria animal research projects need to be approved by the respective national agencies (Ministry of Science and Research for Universities or Landeshauptmann for projects in the Länder). The agencies are supported by experts, who have expertise in the specific scientific field of the project, the writing of protocols (particularly statistical expertise), veterinary practice of the specific scientific field of the project, and stockbreeding.[201] The experts do not form standing committees. In addition, the National Committee for the protection of animals used for scientific purposes advises the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice.

In **Germany,** there is no separate ethical review of a research project involving animals - the ethical considerations are also a part of the authorization procedure. In the course of the procedure, the advice of an animal protection committee (advisory committee) is sought. The majority of members of the advisory committee must have expertise in veterinary medicine, medicine or natural sciences; one third of the members must be nominated by animal welfare organizations[202]. The opinion of the advisory committee is not binding for the competent authority. At the level of the government, the Animal Protection Committee was established. Its aim is to consult the Ministry on animal protection related matters. In particular, it provides advice on animal protection regulations. On the request of the Ministry, it also issues opinions on permissions for experiments on animals.

[201] § 29 (3), Federal Act on the Protection of Animals (Tierschutzgesetz- TSchG), Austria, September 2004. https://www.ris.bka.gv.at/Dokumente/Erv/ERV_2004_1_118/ERV_2004_1_118.pdf

[202] Executive Act on the protection of animals used for experiments or other scientific purposes (Verordnung zum Schutz von zu Versuchszwecken oder zu anderen wissenschaftlichen Zwecken verwendeten Tieren), Austria, 01.08.2013. http://www.gesetze-im-internet.de/bundesrecht/tierschversv/gesamt.pdf

France has fully transposed Directive 2010/63/EU revising Directive 86/609/EEC **on the protection of animals used for scientific purposes**[203] adopted on 22 September 2010 in its Rural and Maritime Fisheries Code. All research projects including experimentation on animals must undergo ethical assessment by one Ethics Committee for Animal Experimentation (Article R214-117 of the Rural and Maritime Fisheries Code). The authorization of the competent authority - the Ministry of Higher Education and Research[204] (*Ministère de l'Enseignement supérieur et de la Recherche*) - is required in order for a research project using animals for scientific purposes to start (Article R214-122 of the Rural and Maritime Fisheries Code[205]). The Ministry bases its decision on ethics assessment which it entrusts to an Ethics Committee for Animal Experimentation (Article R214-124 of the Rural and Maritime Fisheries Code[206]). The authorization cannot be granted without ethical clearance (Article R214-123 of the Rural and Maritime Fisheries Code[207]).

In **Poland,** a new law governing the field of animal experimentation was adopted in 2014 (The Act on Protection of Animals Used for Scientific and Educational Purposes)[208] in order to implement the EU directive. Authorization is carried out by Local Ethics Committees. According to the newly established provisions, these committees will be composed of six members from the fields of biology, pharmaceutical sciences, medicine, agricultural sciences, veterinary sciences with at least degree of Ph.D. and both knowledge and experience with animal research; 3 members from humanities or social sciences, especially from the fields of philosophy, ethics or juristic science, including one member of a non-governmental organisation, that deals with patients' rights protection; and 3 members of non-governmental organisations dealing with animal protection. Apart from the local committees, the law also establishes the National Ethics Committee (it has existed under the former act as well) which gives opinions regarding matters concerning research on animals, draft rules of good scientific practice, and appoints members of the local committees, amongst other tasks.

In **Serbia,** the Law on Welfare of Animals prescribes that all scientific research involving animals should be subject to ethical review. There are two types of bodies that assess animal research. The first is the Ethics Council for the Welfare of Animals Used in Animal Testing, which is a national advisory body, while the second include ethics commissions on local, i.e. institutional level (at clinical centers, at universities, at research institutes). Ethics commissions consist of a veterinarian surgeon, a veterinarian with experience in the breeding of animals to be used in testing, experts with experience of the application of statistics in research, representatives of associations or organizations whose objectives are focused on animal welfare, as well as researchers from related scientific fields. At least one third of the members of the Ethics Commission must be persons who are not employed in the scientific

[203] European Parliament and the Council, Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes, Brussels, 22.09.2010.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063
[204] the Ministry of Higher Education and Research (Ministère de l'Enseignement supérieur et de la Recherche), France.
http://www.enseignementsup-recherche.gouv.fr/
[205] Article R214-122, the Rural and Maritime Fisheries Code (Code rural et de la pêche maritime), France
http://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000027039936&cidTexte=LEGITEXT000006071367&dateTexte=20150121
[206] Ibid.
[207] Ibid.
[208] Act of 15 January 2015 on protection of animals used for scientific and educational purposes (ustawa z dnia 15 stycznia 2015 r. o ochronie zwierząt wykorzystytwanych do celów naukowych lub edukacyjnych), Serbia, 1501.2015.
http://orka.sejm.gov.pl/opinie7.nsf/nazwa/2709_u/$file/2709_u.pdf

organization or other legal entity that conducts animal testing. Details of the assessment procedure are laid down in the Rulebook adopted by the Minister. [209]

In **Spain,** a research project needs to be authorized by a regional competent body (for example in Madrid, it is the Department of Environment and Territorial Regulation, in Andalusia it is the Directorate General of Agricultural and Livestock Production). In order to request the authorization, the researcher first needs to obtain a favourable report of the body responsible for animal welfare at the animal facility and a favourable report of the ethics committee established at the university or a research facility.[210] The committees need to have the expertise and resources needed to carry out its functions. Moreover there should be no conflict of interest in the performance of their duties. [211] The ethics committee must include researchers and other scientific members not directly related to the project and a person with experience and knowledge in animal welfare that has no direct relation with the animal facility centre or the project. [212]

In **the Netherlands,** universities and research institutes require a license before research involving animals can be performed. In December 2014, the Experiments on Animals Act was revised. The 2014 version replaced the one from 1977. The legally required authorization of individual projects is performed by the Central Committee on Experiments on Animals. In order to be authorized, a project proposal first requires approval by the animal experiment ethics committee established at a university or a research institute. The project proposal should provide information to the members of both the DEC and the CCD on procedures that will be used, and the project's scientific or social relevance in a realistic and understandable manner. The evaluation of the ethical acceptability of the proposed procedures requires a justification of the choices that were made during the design of the project. With regards to ethical principles in experiments on animals, guidance is offered by Code of Practice of the Dutch Association for Animal Science .[213]

In addition to laying down the rules of the authorization procedure, national provisions, in line with the directive, grant special protection to certain animal species (e.g. endangered species, non-human primates). In some cases, the laws also explicitly prohibit animal experimentation for certain research purposes, for example testing of weapons, or for the development of tobacco products or cosmetics (this is the case of, for example, Germany and Serbia). At the

[209] Rulebook on conditions for registration of experiments on animals and the keeping of such a register, training programs on welfare of experimental animals, request forms approval of the implementation of experiments on animals, nursing, treatment and killing experimental animals, and about keeping records on holding, reproduction, circulation, or implementation experiments on animals.

[210] Royal Decree 53/2013 laying down basic rules for the protection of animals used for experimental and other scientific purposes are established , including teaching (Real Decreto 53/2013, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia) Spain, 01.02.2013.
http://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-1337

[211] Article 43, Royal Decree 53/2013 laying down basic rules for the protection of animals used for experimental and other scientific purposes are established , including teaching (Real Decreto 53/2013, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia), Spain, of 1 February 2013.
http://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-1337

[212] Article 39, Royal Decree 53/2013 laying down basic rules for the protection of animals used for experimental and other scientific purposes are established, including teaching (Real Decreto 53/2013, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia), Spain, 01.02.2013, p.11370-11421.
http://www.boe.es/buscar/doc.php?id=BOE-A-2013-1337

[213] http://www.proefdierkunde.nl/nl/main/Informatie/Links_downloads

same time provisions do not include an obligation for persons who carry out the ethical review and/or the authorization to participate in any training.

12 BIOBANKING FOR RESEARCH PURPOSES

12.1 EU

The European Commission report, *Biobanks for Europe: A challenge for governance*, gives a comprehensive overview of the European level regulations concerning biobanking in Europe:

"Biobanking is governed under the general regulatory framework for biomedical research. This is a mosaic of formal legal instruments and regulatory bodies put in place at national and European levels, as well as more informal types of governance tools and instruments such as professional guidelines and best practice. Regulation of biomedical research consists of binding and non-binding legal instruments at both national and European levels. This is in the form of specific law for medical research – for example the Council of Europe Oviedo Convention 1997 – and more general legal instruments – such as human rights and data protection law – some of which have relevance for biobanking. Responsibility for the oversight of research and ensuring compliance with the legal requirements has largely been delegated to national bodies, such as research ethics committees.

This has resulted in a diversity of legal requirements for biobanking activities across Europe but also at national levels, as there is no one binding instrument that applies specifcally to biobanks. This complexity places researchers, who collaborate across Europe, at risk of operating unlawfully if they share research data and samples across borders where different laws are in force with-out operating due diligence. Biobank managers have expressed concern that the current regulatory framework for human biobanks within Europe creates uncertainty and inhibits the building of biobank infrastructure.82 In addition to diversity in the legal requirements, national research ethics committees may have different requirements for collaborative research. This may have implications for research consortia that wish to share samples and data derived from different biobanks.

As well as uncertainty about the legal requirements that might apply for cross- border transfers, there are also areas, such as the use of tissue for research purposes, which are central to biobanking, that are not covered by binding European legal instruments. This has lead to differences in the formal legal requirements for the research use of tissue and data. However, there have been a number of advisory opinions by groups such as the Art. 29 Working Group that have developed opinions to help ameliorate these differences.

Therefore, identifying the legal instruments that apply to biobanking within Europe results in a complex picture of requirements and enforcement measures. The aim of this section is to give an overview of this complexity by discussing the legal requirements for biobanks at the European level and to provide a broad outline of the regulatory bodies that are responsible for ensuring best practice for biobanking activities."

The report continues to list the relevant structures from the Council of Europe, The European Union, The Clinical Trials Directive, and The Data Protection Directive.[214]

[214] Biobanks For Europe.
http://www.coe.int/t/dg3/healthbioethic/Activities/10_Biobanks/biobanks_for_Europe.pdf

12.2 NATIONAL LEVEL

Biobanking is not regulated by a specific piece of legislation in **Austria**. The practice is in line with data protection rules. The precondition for taking samples is free and informed consent. Participants are informed of their right to withdraw consent. The consent is specific in so far as participants consent to the use of their sample for research. The samples are coded. The researcher only uses pseudo-anonymised samples. Access to the un-coded samples is limited. Individual research projects with pseudo-anonymised samples are reviewed by the Research Ethics Committee of the individual biobank. Participants can monitor the activities of the biobank through information provided over the Internet. In practice, banked tissue is usually residual material from a clinical setting which is banked for future research. In the event that there are important findings relevant for clinical treatment, donors would be contacted. In this case, the right to know would usually prevail over the right not to know. The fact that a donor is deceased does not change anything with regard to previous informed consent requirements.

In **Germany** there are no specific statutory provisions for biobanks for research purposes. The most comprehensive analysis of legal situations of biobanks has been offered by the German Ethics Council in the opinion on human biobanks[215]. In principle, according to the German Ethics Council, biobanks are subject to the same precept as research on human beings in general.

- "the fundamental rights of the person affected are enshrined in the Basic Law and must be respected; their dignity and their right to life and physical integrity must be respected just like their right of personality and their right to informational self-determination. The constitutionally guaranteed freedom of research does not remove the obligation to observe these fundamental rights. Consequently, encroachments upon bodily integrity – provided they are not authorized by statute – require the express consent of the persons affected. This consent must be preceded by appropriate information on the purpose, significance and implications of the encroachment (informed consent). If, therefore, blood or tissue samples are taken from a person for the specific purpose of research and/or storage in a biobank, the donor must give his informed consent. The same applies to the collection and the processing of personal data for research purposes: without the consent of the persons affected, this is unlawful, except where the statute provides otherwise."
- "[w]ith specific regard to the requirement of informed consent to the use of biomaterials and biological data, therefore, the high priority of freedom of research must be taken into account when interests are weighed (…). The data protection Acts of the Federal Government and the Federal Länder make it possible to give priority to scientific research in a weighing of legal interests even where particularly sensitive and therefore specially protected data, such as information on health or on sex life, are to be processed. Although the provisions are sometimes inconsistent (...), it is the fundamental requirement for the use of data that the scientific interest must outweigh the interests of the persons affected, and that the research purpose can be achieved only in this way, or alternatively only with disproportionate expense and effort. This weighing of interests may also be applied with regard to the use of bodily materials."
- "[t]he basis for biobank research (…) is that personal data may be collected and used only for purpose specified in advance. (…)"

[215] German Ethics Council (Deutsche Ethikrat), Human biobanks for research, 2010. http://www.ethikrat.org/files/der_opinion_human-biobanks.pdf

The German Ethics Council proposed a five-pillar concept for biobank legislation. The five pillars include the following:

- the introduction of biobank secrecy,
- the definition of permissible use,
- the involvement of ethics commissions,
- quality assurance in connection with data protection,
- transparency of the aims and procedures of a biobank.

The term used in **France** for "biobank" is biolibraries (biothèques) which has a different conceptual signification. French legislation never refers to biolibraries nor biobanks. It only refers to "collections of human biological samples" and indirectly on their gathering in what would be called in common language a biolibrary.
According to the Article L1243-3 of the PHC, "collections of human biological samples" means the gathering, for scientific purposes, of biological samples and derivatives thereof taken from a group of persons identified and selected based on clinical or biological characteristics of one or more members of the group.

The legislature chose to focus on the collection and not on the institutions of storage in order to monitor all samples collections existing (i.e. collections in what would be called "biobanks" but also isolated collections in other institutions).

The bio libraries are indirectly defined in the general definition of institutions conserving human biological samples in the Article L1243-3 of the PHC (i.e. any institution that has made a prior declaration to the Minister in charge of research may, for purposes of its own research programs, ensure the conservation and the preparation for scientific purposes of tissues and cells from the human body and the preparation and storage of organs, blood, its components and its derivatives) and in the general definition of institutions conserving human biological samples for the purpose to give them away to others that will be conducting research projects using them in the Article L1243-4 of the PHC (i.e. any organism that ensures the conservation and the preparation of tissues and cells of the human body to give away, for scientific purposes).

In **Poland,** there are no comprehensive provisions regarding biobanks for research purposes. According to Article 2 (1) point 1 of the act of 1 July 2005 on recovery, storage and transplantation of cells and tissues[216], "tissue and cell bank" shall be understood as "Organizational unit, which gathers, sterilises, stores and distributes cells and tissues. Such unit may also recover and test both tissues and cells". However, according to article 25, banks of tissues and cells are established for the purpose of transplantation and not for research.

In 2011, the Panel for Molecular Genetic Research and Biobanking (*Zespół ds. Molekularnych Badań Genetycznych i Biobankowania*) was established. Its aim is, among other things, to prepare proposition on:

- the establishment of a national genomic biobank;
- legislation on biobanks, which would be based on OECD Guidelines on Human Biobanks and Genetic Research Databases;

[216] Act of 1 July 2005 on recovery, storage and transplantation of cells and tissues (ustawa z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów), Poland, 01.07.2005.
Unofficial English translation: http://www.poltransplant.pl/Download/prawo/Polish_Transplantation_Act_2005.pdf
Polish: http://isap.sejm.gov.pl/DetailsServlet?id=WDU20051691411

- Poland's membership in the Biobanking and Bimolecular Resources Research Infrastructure (BBMRI).

In 2012 the Panel published a report on the topic of genetic tests for medical purposes with a proposal for legislation in this area.[217]

As far as the protection of genetic data is concerned, according to article 27 (1) of the Act of 29 August 1997 on the Protection of Personal Data[218] it is, as a general rule, forbidden to process information on genetic code. Subsection 2 stipulates conditions which should be met in order to process such information. The act in question does not determine how the genetic code shall be understood.

In **Spain,** the functioning of biobanks is regulated by Law 14/2007[219] and Royal Decree 1716/2011 establishing the basic requirements for authorization and operation of biobanks for biomedical research and treatment of biological samples of human origin, and the functioning and organization of the National Register of Biobanks for Biomedical Research.[220] According to the Spanish legislation, biobanks are "public or private establishments, non-profit, which house a collection of biological samples, intended for diagnostic or biomedical research and organized as a production unit with quality criteria, order and destination." Biobanks must have a scientific committee as well as an external ethics committee. Royal Decree 1716/2011 establishes the requirements of informed consent. This includes a waiver of any economic, financial or discretionary right to the results or potential benefits that may arise directly or indirectly from research carried out with the sample donated. The law lists the information that should be included in the consent form for the collection, storage or conservation and utilization of biological samples of human origin for biomedical research. Samples and associated data shall be transferred only anonymously or de-identified. In order to obtain authorization, registration in the General Register of the Spanish Data Protection Agency or, where appropriate, in the register of the regional data protection agency is required. In the course of registration, measures planned to protect personal data should be set out. Law 14/2007 establishes that "Every person has the right to be informed of his or her genetic data and other data of a personal nature that are obtained in the course of a biomedical research, in accordance to the terms that he or she assented. The same right is recognised to the person who has provided, with the aforementioned purpose, biological samples or when other biological materials are obtained from these".[221] The law also recognizes the right of the person not to know these data, if indicated in the informed consent. However, if this information is necessary in order to avoid serious damage to the subject's health or that of their family members, a close family member or a representative may be informed of the data

[217] Zespół ds. Molekularnych Badań Genetycznych i Biobankowania, „Testy genetyczne dla celów zdrowotnych", Warszawa 2012.

[218] Act of 29 August 1997 on the Protection of Personal Data (Ustawa z dnia 29 sierpnia 1997 r. o ochronie danych osobowych), Poland, 29.08.1997.
http://isip.sejm.gov.pl/DetailsServlet?id=WDU19971330883

[219] Law 14/2007 of 3 July 2007 on Biomedical Research. www.boe.es/buscar/act.php?id=BOE-A-2007-12945&tn=1&p=20110602&vd=#tviii

[220] Royal Decree 1716/2011 establishing the basic requirements for authorization and operation of biobanks for biomedical research and treatment of biological samples of human origin, and the functioning and organization of the National Register of Biobanks for Biomedical Research (Real Decreto 1716/2011, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica),Spain, 2.12.2011.
www.boe.es/buscar/doc.php?id=BOE-A-2011-18919

[221] Article 4.5, Law 14/2007, Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007.
http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf

exclusively necessary to this end, after consulting with the clinical ethics committee. The Decree lays down rules on the post-mortem use of samples. In general, the collection and use of biological samples from deceased persons is allowed if they arranged so in life or did not express their opposition. To this end, it is necessary to investigate the existence of advance directives, and in their absence, to consult the closest relatives of the deceased and the professionals who treated them at the hospital - this inquiry will be recorded. The scientific committee and the external ethics committee of the biobank must guarantee that safeguards are taken against discrimination and stigmatization, both applied to researchers and donors.

In **Serbia,** there is no specific legal act that covers biobanking. Regulations pertaining to conducting research using human tissues and the conditions of it are regulated by the Law on transplantation of cells and tissues.[222] Scientific research on cells and tissues is permitted solely for the purpose of preserving and improving human health. Scientific research on cells and tissues can be performed if the research is carried out on animals or if the desired results cannot be achieved in some other way. During scientific research, modern standards of medical science and medical ethics must be respected. Research work is allowed on the hematopoietic cells of the peripheral blood, the blood from the placenta, stem cells from bone marrow, reproductive cells, tissues and cells of a foetus and adult stem cells and embryonic organisms that do not meet the requirements and criteria for use for treatment, which are not sufficient for treatment procedure, or which are not needed for treatment procedure of a particular patient. Scientific research on cells or tissues requires a written consent of the person from whom the cells and tissues are taken or obtained.

As regards authorization, the Minister of Health issues a permit for conducting scientific research on cells or tissues to a medical institution, or other legal entity which meets legal requirements for conducting scientific research, or to a principal investigator, on the basis of the opinion of the Directorate for Biomedicine. The health care institution or other legal entity must have a principal investigator responsible for conducting scientific research.

The permit is issued for a specific kind, method and duration of scientific research. The Directorate for Biomedicine monitors the implementation of the scientific research and submits a report to the Minister at least once a year. The Minister may revoke the license prior to the expiration of the period for which the license is issued, if, on the basis of the report of the Directorate for Biomedicine, he or she finds that the implementation of the scientific research is in contradiction with the issued permit, or that it is contrary to the rules of medical science and professional ethics. The Minister can extend the period for which the license was issued. The Minister issues a decision on granting a permit for conducting scientific research on cells or tissues within 90 days from the date of application. The process of making the decision on issuing or revoking permits is subject to the law governing the general administrative procedure. The decision is final in terms of administrative proceedings and an administrative dispute can be initiated against the decision. The Principal Investigator has to submit a copy of the written consent to the Directorate for Biomedicine, in addition to other documentation necessary for granting permission for research. The Minister prescribes the format of the Statement of Consent. The Statement of Consent is kept in the medical institution in which the cells or tissues are taken, for 30 years from the date of issue of the statement.

[222] Law on transplantation of cells and tissues (Zakon o transplantaciji ćelija i tkiva), Official Gazette of Republic of Serbia, no. 72/2009. Serbia, 31.08.2009.
www.rfzo.rs/download/zakoni/Zakon_celije_tkiva.pdf

In **the Netherlands,** the statutory rules concerning research on body material are still under development.[223] In recent decades, hospitals and the research community have put a lot of effort into establishing *de novo* biobanks (prospective collections of patient material) for broad research goals, especially to enable future studies. Guidelines on how a biobank shall function are laid down in the Code for Proper Secondary Use of Human Tissue[224] The key points described in the Code are: safety, carefulness, responsibility, traceability, informed consent, and storage periods. The 'code for dealing responsibly with human tissue in the context of health research'[225] explains that responsibility refers to the responsibility of the health care professional in obtaining the specimen, the responsible custody of a collection of human tissue, the responsibility of the healthcare institution where procedures to obtain specimens of human tissue for health research takes place and the responsibilities of the researcher.

The AMC/VUMC code of conduct (2014) explains the code as follows:

> According to the Code, research on anonymous (i.e. untraceable) body material is permitted unless the person in question has at any time indicated that he or she objects to this further use. For storing and using human tissue for research that is not anonymous (such as encoded tissue), the informed consent of patients is required, unless this is impossible (e.g. the patient is deceased) or reasonably impracticable (e.g. very large cohorts of patients). Explicit informed consent should always be obtained before material is taken specifically for the purpose of research. In most cases, consent can be of a broad nature. If there is a substantial likelihood of findings being produced that are of clinical value to the health or wellbeing of the person concerned and are actionable ("individual research findings"), this issue should be specifically mentioned to potential research participants. Research participants should be informed about the "feedback policy" of the researcher/biobank, the possibility to indicate that they would prefer not to be informed about new findings, and that this preference can be overruled if serious harm to themselves or their family members can be prevented. If patients find this policy difficult to accept, they should not participate. Ethical committees are usually involved at an early stage in the procurement and use of body material for research purposes (AMC/VUMC, 2014).

All Dutch university medical centers participate in the collaboration on biobanks, in the String of Pearls initiative.[226] The String of Pearls Initiative complies with the requirements for biobanks based on the Compiled Standard model for Biobanks, based on ISO/IEC 17025, OECD, REC(2006), ISBER, NCI and ISO Guide 34. This International Standard specifies the general requirements for the competence to carry out acquisition, maintenance and provision of biological materials and validation/authentication. It covers validation/authentication performed using standard methods, non-standard methods, and biobank-developed methods.

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[223] AMC and VUMC, Research Code, Scientific integrity at VUmc and AMC. Opgehaald van AMC Research Code, 2014, www.amc.nl/web/AMC-website/Research-Code/3-Respect-for-human-subjects.htm?tab=533183

[224] Code for Proper Secondary Use of Human Tissue (Goed gebruik), The Netherlands, 2001. www.federa.org/codes-conduct

[225] Federa .(2011) Code of conduct for dealing with responsibility with human tissue in the context of health research – Human tissue and medicao research: code of conduct for responsible use. The Netherlands. http://www.federa.org/sites/default/files/digital_version_first_part_code_of_conduct_in_uk_2011_12092012.pdf

[226] http://www.erasmusmc.nl/research/expertise/samenwerkingen/parelsnoer/?lang=en

13 EMBRYO AND STEM CELL RESEARCH

13.1 EU

The EU law does not provide a definition of a human embryo. Court of Justice of the European Union (CJEU), in one of its judgments, coined the definition of a human embryo for the purpose of application of Directive 98/44 on the legal protection of biotechnological inventions[227]. According to the judgment, the term "human embryo" in Article 6(2) of that directive must be regarded as designating an autonomous concept of European Union law and must be interpreted in a uniform manner throughout the territory of the Union. It is important to highlight that the Brüstle judgment stated that "the purpose of the [Biotech] Directive is not to regulate the use of human embryos in the context of scientific research. It is limited to the patentability of biotechnological inventions".[228] In other words, the Court did not deal with the question of whether such research can be carried out and whether it can/should be funded. A more recent judgment clarified how article 6(2)(c) of the Directive should be interpreted in the context of the abovementioned directive. According to this judgment "unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a 'human embryo', within the meaning of that provision, if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine".[229]

Human embryonic stem cell research in Europe is subject to national laws and regulations that vary between countries.

As stated in the Commission's Communication,[230] EU research programmes are adopted without prejudice to Member States' activities in the field of research (this is due to the fact that research is a parallel competence, Article 4(3) Treaty on the Functioning of the European Union). In Horizon 2020, it has been agreed that human embryonic stem cell research can be financed under the EU programme, restricted to research subsequent to the establishment of stem cell lines. Moreover, EU projects must follow the laws of the country in which the research is carried out.

According to Article 19(4) of the act on Horizon 2020 "research on human stem cells, both adult and embryonic, may be financed depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all Member States. No activity shall be funded in a Member State where such activity is forbidden."[231]

13.2 NATIONAL LEVEL

[227] European Parliament and the Council, Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, Brussels, 06.07.1998.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0044

[228] Court of Justice, Judgment of the Court (Grand Chamber) of 18 October 2011. Oliver Brüstle v Greenpeace, 18.10.2011 (C-34/10).
http://curia.europa.eu/juris/document/document.jsf?text=&docid=111402&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=314944

[229] Court of Justice, Judgment of the Court (Grand Chamber) of 18 December 2014, International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trade Marks (C-364/13).
http://curia.europa.eu/juris/document/document.jsf?text=&docid=160936&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=15251

[230] European Commission, Communication from the Commission on the European Citizens' Initiative "One of us", 28.05.2014.
http://ec.europa.eu/transparency/regdoc/rep/1/2014/EN/1-2014-355-EN-F1-1.Pdf

[231] European Parliament and the Council, Regulation (EU) No 1291/2013 of 11 December 2013 establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and repealing Decision no 1982/2006/EC, Brussels, 11.12.2013.
http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf

The rules on human embryonic stem cell research, as well as the level of detail, vary between EU countries. Moreover, some EU member states still lack comprehensive regulation in this field.

In **Austria,** human embryonic stem cell research is not prohibited; only the procurement of human embryonic stem cells is banned by the Act of Artificial Procreation (§ 9).[232] The term "embryo" is not defined in the national legislation. The legislation uses the term "viable cells". Human embryonic stem cell research is totally excluded from public funding on ethical grounds. Official documents on the prohibition of financing of human embryonic stem cell research of Austrian funding organizations are however not available. The Austrian negotiation position as documented by the Statement to the Minutes of the 2476th meeting of the Permanent Representatives Committee (Part 1) and the Council "Competitiveness" on 02/03 December 2013 gives evidence for this.[233]

On the grounds of § 5 **German** Stem Cell Act (StZG)[234] embryo stem cell research can only be carried out, when it is scientifically justified that:

i. "such research serves high-ranked scientific purposes, which may provide new knowledge in the area of basic research or deepen medical knowledge and lead to development of diagnostic, preventive or therapeutic techniques for humans.
ii. pursuant to the current level of scientific and technological knowledge:
    - the questions stated in research project have been answered as far as possible by means of *in vitro* models using animal cells or by means of animal experiments;
    - the new scientific knowledge can only be acquired using embryonic stem cells".

The definition of an embryo is included in German Embryo Protection Act (Embryonenschutzgesetz, ESchG)[235] according to which an embryo should be understood as "fertilized ovum from the moment of karyogamy (cell union), that is capable of further development, as well as any totipotent cell extracted from an embryo, which under certain conditions is capable of dividing and developing into an individual". The creation of embryos for research purposes is not allowed, but on the grounds of § 4 of StZG they can be imported, when specific requirements are fulfilled.

In **France**, research on embryo was recently permitted by the Law No. 2013-715 of August 6, 2013 amending Law No. 2011-814 of 7 July 2011 on bioethics by allowing under certain conditions research projects on embryos and embryonic stem cells. According to Law No. 2011-814 of 7 July 2011 on bioethics (Title VII: research on embryos and embryonic stem cells) such research was prohibited but allowed under certain conditions notwithstanding. These laws have been codified in the French Public Health Code (PHC).

[232] § 9, Act of Artificial Procreation (Gesamte Rechtsvorschrift für Fortpflanzungsmedizingesetz), Austria, 03.03.2015. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10003046

[233] See Annex 1: Austrian Statement to the Minutes of the 2476th meeting of the Permanent Representatives Committee (Part 1) and the Council "Competitiveness" on 02/03 December 2013.

[234] Stem Cell Act (Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen), Germany, 28.06.2002. http://www.gesetze-im-internet.de/bundesrecht/stzg/gesamt.pdf

[235] Embryo Protection Act (Gesetz zum Schutz von Embryonen), Germany, 13.12.1990. http://www.gesetze-im-internet.de/bundesrecht/eschg/gesamt.pdf

Now, according to Article L2151-5 of the PHC, no research on human embryos or embryonic stem cells can be undertaken without authorization. A research protocol conducted on human embryos or embryonic stem cells derived from a human embryo can only be permitted if:
- the scientific relevance of research is established,
- the research, fundamental or applied, is part of a medical purpose,
- in the state of scientific knowledge, this research cannot be conducted without using embryos or embryonic stem cells,
- the project and the protocol implementation conditions comply with ethical principles for research on embryos and embryonic stem cells.

According to Article 214-1 of the French Criminal Code, the fact to implement eugenic practices aimed at organizing the selection of persons is punished by thirty years' imprisonment and a 7.5 million euro fine. According to Article 214-2 of the Criminal Code, the fact to conduct an intervention seeking to raise a child genetically identical to another living or deceased (ie cloning) is punishable by thirty years' imprisonment and a 7.5 million euros fine.

According to Article L2151-5 of the PHC, research protocols are authorized by the Biomedicine Agency (*Agence de Biomédecine*) after verification that research protocols respect the conditions reported for the previous question. The decision of the Biomedicine Agency is communicated to the Ministers for Health and Research who may seek review of the record used as the basis for the decision.

The ethics board of the Biomedicine Agency *(conseil d'orientation de l'Agence de la biomédecine*) ensures the consistency of the medical and scientific policy of the Agency, and enforces regulatory and ethical principles in all its activities. It reviews all research protocols prior to authorization.

In Poland to date, there have been no legal rules regarding the handling of embryos. Article 18.1 of the draft law on the treatment of infertility prohibits the creation of embryos for purposes other than medical procedures of assisted procreation. Moreover, it is prohibited to create chimeras, hybrids, as well as to perform changes in the human genome. Finally, the law prohibits the creation of embryos with genetic information identical to that of another embryo, fetus, a human being or deceased person.[236] The law has not been yet adopted. An interesting case has recently been submitted to the prosecution that concerned the destruction of embryos.[237] The proceedings have been discontinued, due to the fact that there are no legal rules that would penalize such a behavior.[238]

In **Serbia,** embryo research is allowed under specific terms and conditions. Two laws, namely the Law on transplantation of cells and tissues[239] and the Law on infertility treatment by

[236] Act of xx on the Treatment of Infertility (Ustawa z xx o leczeniu niepłodności), Poland, 16 July 2014. http://legislacja.rcl.gov.pl/docs//2/230033/230041/230042/dokument119906.pdf
[237] The case concerned the destruction of a container with embryos kept at a private clinic. After the clinic ceased to perform in-vitro procedures, it stopped purchasing the substance required for the storage of embryos, which led to their destruction.
[238] Gazeta Prawna, Destroying embryos is not a criminal offence (Niszczenie embrionów nie ma znamion czynu zabronionego), Poland, 16.01.2014.
http://serwisy.gazetaprawna.pl/zdrowie/artykuly/770920,in-vitro-niszczenie-embrionow-nie-ma-znamion-czynu-zabronionego.html
[239] Law on transplantation of cells and tissues (Zakon o transplantaciji ćelija i tkiva), Official Gazette of Republic of Serbia no. 72/2009, Serbia, 03.09.2009.
www.rfzo.rs/download/zakoni/Zakon_celije_tkiva.pdf

applying the procedures of biomedically-assisted fertilization[240] regulate this field. Scientific research in human early embryos is allowed only with a mutual written consent of the spouses or domestic partners who undergo the biomedically assisted reproduction procedure. The creation of embryos for research purposes or stem cell procurement is forbidden. It is also prohibited to offer or donate reproductive cells or embryos for the purpose of acquiring financial or any other benefit; to trade reproductive cells or embryos, or use the reproductive cells or embryos that were obtained by trade in a biomedically assisted reproduction procedure; to mediate in the offering, donation, or trade of reproductive cells or embryos for the purpose of acquiring financial or any other benefit. The definition of an embryo is provided in Article 3 of Law on infertility treatment. According to this provision, "embryo is a fertilized egg (the zygote) which divides within the first 56 days, except for the time during which the development was stopped, capable of further development from the moment of the union of two gametes and thereafter; every totipotent embryonic stem cell that can continue to divide and develop into an individual provided that the necessary conditions are met."

The **Spanish** Law on Biomedical Research contains comprehensive provisions on embryo research. According to the law, an embryo is defined as the stage of embryonic development spanning from the time in which the fertilized egg is in the uterus of a woman until the onset of organogenesis occurs, and ending at 56 days from the date of fertilization, except those in which the development could have been stopped. The pre-embryo is the in vitro embryo formed by the group of cells resulting from the progressive division of the egg from being fertilized for up to 14 days later.[241] Embryo research is allowed with some conditions expressed in Law 14/2007:[242] "1. Human embryos that have lost their capacity for biological development, as well as dead human embryos or foetuses, may be donated for biomedical research or other diagnostic, therapeutic, pharmacological, clinical or surgical purposes. 2. The interruption of a pregnancy shall never have as its purpose the donation and later use of embryos, foetuses or their biological structures (…). 3. The foetuses that are prematurely and spontaneously expelled shall be clinically treated while they remain biologically viable with the sole purpose to favour their development and vital autonomy. 4. Before proceeding to any intervention on human embryos that have lost their capacity of biological development or on dead embryos or foetuses, a record shall be made by the corresponding medical personnel that such circumstances have taken place". The use of oocytes and pre-embryos is also regulated by law[243]. Such use requires the consent of the persons from whom they derive, who can revoke it at any moment without affecting the research undertaken. The donation of oocytes and pre-embryos is governed according to the provisions in Law 14/2006 on Assisted Human Reproduction Techniques[244]. The creation of human pre-embryos and embryos exclusively for experimentation purposes is prohibited.[245]
In order for the research to proceed, it requires a favourable report by the Commission of Guarantees for the Donation and use of Human Cells and Tissues as well as the authorization

[240] Law on infertility treatment by applying the procedures of biomedically-assisted fertilization (Zakon o lečenju neplodnosti postupcima biomedicinski potpomognutog oplođenja), Official Gazette of the Republic of Republic of Serbia no. 72/2009, Serbia, 2009.
www.paragraf.rs/propisi/zakon_o_lecenju_neplodnosti_postupcima_biomedicinski_potpomognutog_oplodjenja.html
[241] Article 1, Law 14/2007, Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007.
http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf
[242] Article 28, Law 14/2007, Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007.http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf
[243] Article 32, Law 14/2007, Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007.
http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf
[244] BOE n. 126, May 27th 2006, p.19947-19956. http://www.boe.es/buscar/doc.php?id=BOE-A-2006-9292
[245] Article 33, Law 14/2007, Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007.
http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf

of the corresponding autonomous or state authority. The team responsible for the authorised project must communicate its result both to the entity that provided the authorisation to the submitted project, as well as to the Commission of Guarantees for the Donation and use of Human Cells and Tissues. In the case of oocytes, the consent of the donors shall make express reference to its authorisation for the use of a specific technique or techniques that are going to be applied to the oocytes that are object of the donation. For that purpose, the health professionals who are responsible for obtaining these oocytes shall provide the donors with appropriate information prior to gaining the consent and keep a clear written record of all of this.[246] If oocytes or pre-embryos are used, indication and justification for their number and origin and the informed consent document signed by the donors or parents is required. Financial remuneration to the donors is not allowed, only compensation for the donation of oocytes.

In the **United Kingdom**, research on embryos is permitted in specific circumstances and is largely regulated by the "Research on human embryos is allowed for certain purposes, outlined in the Human Fertilisation and Embryology Act (1990)[247] and the subsequent Human Fertilisation and Embryology (Research Purposes) Regulations 2001[248]:

- to promote advances in the treatment of infertility
- to increase knowledge about the causes of congenital disease
- to increase knowledge about the causes of miscarriages
- to develop more effective techniques of contraception
- to develop methods for detecting the presence of gene or chromosome abnormalities
- to increase knowledge about the development of embryos
- to increase knowledge about serious disease
- to enable any such knowledge to be applied in developing treatments for serious disease
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The use of embryos in stem cell research can be carried out only with authority from the HFEA. Licences are granted only if the HFEA is satisfied that any proposed use of embryos is absolutely necessary for the purposes of the research.

Licensed research can only take place on embryos created *in vitro:* embryos that have developed from eggs fertilized outside the body. Most embryos used in UK stem cell research are embryos initially created for use in fertility treatment, but not used. These 'surplus' IVF embryos, if donated with the full consent of the parents, can be used for research. Licensed research can only take place on embryos up to 14 days. Stem cells are isolated from the blastocyst much sooner than this – at 5 to 6 days.

A 2008 amendment allowed the HFEA the power to grant licences to add limited amounts of animal cells to human ones to make hybrids such as true chimeras, true hybrids and transgenic human embryos. Any such licences must be for specific research purposes. Human reproductive cloning is illegal in the UK. As a result of the Human Reproductive Cloning Act (2001) nobody in the UK is allowed to use cell nuclear replacement, or any other technique, to create a child.

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[246] Article 32, Law 14/2007, Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007. http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf

[247] Human Fertilization and Embryology Act, United Kingdom, 1990. http://www.legislation.gov.uk/ukpga/1990/37/contents

[248] Human Fertilisation and Embryology (Research Purposes) Regulations, United Kingdom, 2001 http://www.legislation.gov.uk/uksi/2001/188/pdfs/uksi_20010188_en.pdf

The Human Tissue Act 2004 regulates the use of human biological materials including the storage, use and removal of human tissue and cells, and is overseen by the Human Tissue Authority.

The regulatory pathway for stem cell research in the UK is well established, and is documented for different research scenarios (human stem cells only) in the UK Stem Cell Toolkit.

Regulators include the Human Tissue Authority (HTA), the HFEA and the Medicines and Healthcare products Regulatory Agency (MHRA), all of which work closely in areas of mutual interest. Regulators also hold joint advisory meetings to provide guidance to operators. In 2010, there were proposals to abolish the HFEA and transfer regulation of stem cell research to the UK Department of Health. The outcome of these proposals is uncertain at the time of writing.

The Gene Therapy Advisory Committee (GTAC) is a research ethics committee that considers all proposals for research on human subjects using cells from human stem cell lines. Independent bodies such as the Nuffield Council of Bioethics and the Royal Society have also examined and issued reports on ethical issues relating to stem cell research. "

In **the Netherlands,** the Embryo Act[249] prohibits the generation of embryos specifically for scientific research. According to the Act, gametes and embryos that are no longer going to be used in a woman's own pregnancy (for example, following IVF treatment) can, however, be used in donation, culturing embryonic stem cells as well as scientific research. The consent of those individuals from whom the gametes were taken or for whom the embryo was originally intended is required. Under the Embryos Act, an embryo is defined as "a cell or a complex of cells with the capacity to develop into a human being." It is noteworthy that the Embryo Act is periodically evaluated. The second evaluation of the Embryo Act was carried out in September 2012. The overall conclusion was that the Act is well observed. However the report highlighted the issue of the obstruction of scientific research as a result of the ban on the creation of embryos. It was argued that it might place the Netherlands at a disadvantage.

14 GENETIC TESTING

14.1 EU

Sirpa Soini provides an exhaustive overview of the status of genetic testing legislation in the EU:

"According to Article 168 of the Treaty on the Functioning of the European Union (later referred to as TFEU), a high-level human health protection shall be ensured in the definition and implementation of all Union policies and activities. Still, the actions of the EU in the health field are, under EU law, complementary to those of the member states, and limited to the common safety concerns as defined in Article 168.4 TFEU, including setting high standards of quality and safety for medicinal products and devices for medical use. For instance, Directive (98/79/EC) on in vitro diagnostics devices stipulates essential

[249] Act containing rules relating to the use of gametes and embryos (Wet van 20 juni 2002, houdende regels inzake handelingen met geslachtscellen en embryo's (Embryowet)), The Netherlands, 20.06.2002. www.ccmo.nl/attachments/files/embryos-act.pdf

requirements of genetic tests that are put on the market or on the service. It is not applied to in-house tests and tests only for research purposes. The IVD directive, however, focuses on the safety aspect of the genetic tests as a device, as a product, when used for medical purposes, while aspects related to the quality, validity and utility of such a test are not governed.

Moreover, Directive 98/44/EC on the legal protection of biotechnological innovations is applied to conditions under which genetic tests can be patented. For ethical and legal issues pertaining patenting and licencing in genetic testing, see Soini et al. (2008).

Data Protection Directive 95/46/EC is applicable on handling the genetic data. Under Article 8(1), data concerning health is regarded as 'sensitive data' in the directive, covering hence health-related genetic data. EU's Article 29 Data Protection Working Party adopted a Working Document on Genetic Data on March 17, 2004, claiming that genetic data has extremely singular characteristics compared to health data and thus calls for reinforced legal protection. It was noticed, however, that genetic data should not be seen in a reductionist way, i.e. having a universal explanatory value of human life. All in all, many key challenges of the use of genetic testing are discussed in the document, even though the argumentation reveals strong genetic exceptionalism. Interestingly, at the same time, a working group invited by the European Commission gave 25 recommendations on the ethical, legal and social implications of genetic testing (EC Expert Group 2004) and stated that the notion of genetic exceptionalism is inappropriate and should thus be avoided. Instead, the EC Expert Group claimed equally high protection for all medical data.

In November 2010, European Commission made an initiative to start revisiting the legal framework for data protection. Amongst the issues is whether genetic data should be explicitly considered as 'sensitive data', widening it then to also to other than health information. The Commission is anticipated to give a proposal for a new legal framework in the early 2012. Given the current ambiguity of the EU stand, it will be interesting to see what kind of an input the Article 29 Data Protection Working Party is going to give on this round, and whether it will affect the treatment of genetic information in the EU.

In the primary law of EU, Article 3 of the EU Charter of fundamental rights (2010/C 83/02) captures the core rules on the right to the integrity of the person as follows:

1. Everyone has the right to respect for his or her physical and mental integrity
2. In the fields of medicine and biology, the following must be respected in particular:
    - The free and informed consent of the person concerned, according to the procedures laid down by law
    - The prohibition of eugenic practices, in particular those aiming at the selection of persons
    - The prohibition on making the human body and its parts as such a source of financial gain
    - The prohibition of the reproductive cloning of human beings

In addition, Article 21 of the Charter bans discrimination:

Any discrimination based on any ground such as sex, race, colour, ethnic or social origin,genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited.

Despite the lack of specific genetic legislation at EU level, data protection and discrimination provisions are relevant when handling and using genetic data: genetic data pertaining health is 'sensitive data' under EU data protection directive, and is thus to be treated confidentially. Likewise, discrimination based on genetic features is prohibited in the EU member states.

The Council of Europe has been active in the bioethical arena since 1985. Both the Parliamentary Assembly and the Committee of Ministers have issued tens of recommendations in this field. The Committee of Ministers' Recommendation No. R (97) 5 on the protection of medical data is applicable to the collection and automatic processing of medical data, genetic data included. The expression of genetic data is defined to 'refer to all data, of whatever type, concerning the hereditary characteristics of an individual or concerning the patterns of inheritance of such characteristics within a related group of individuals'. It contains special provisions on collection, procession and use of genetic data, and on incidental findings of genetic analyses. All in all, approach to the use of genetic data in the recommendation is similar to other medical data, with a few exceptions. For instance, the recommendation states that the use of genetic data for forensic purposes shall be governed by law. Further, it is recommended that the person subjected to genetic analysis should be informed of unexpected findings, if this is not forbidden in the domestic law, the person has asked this information, and the information is not likely to cause serious harm on his or her health or to his or her close relatives. The Committee of Ministers' Recommendations are not binding, but they often have impact as soft law instruments since they reflect the collective position of the governments of the member states (Benoît-Rohmer and Klebes 2005, p. 108-109). Indeed, the recommendation has been referred to at least in the Finnish legislative procedures.

The Council of Europe Convention on Human Rights and Biomedicine (ETS No. 164, 1997, later referred to as the Biomedicine Convention) is often claimed to be the first international legally binding instrument in the field of biomedicine. However, as subject to the international treaty law, it becomes a binding national law in a certain country only if the country ratifies it. For instance, Germany and the UK have not even signed the Biomedicine Convention, and France has only signed it. Yet, at the moment, 28 countries have ratified it.[3] The Biomedicine Convention has been later completed by various protocols. These protocols are subject to same ratification procedures as the Biomedicine Convention itself.

The Biomedicine Convention has relevant provisions on genetic testing. Article 12 of the Convention limits the use of predictive genetic tests to "*tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a*

disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling". Thus, Article 12 is legally binding rule in the 28 countries that have ratified it.

According to article 23 of the Biomedicine Convention, countries bound by it shall provide appropriate judicial protection for infringements of the rights and principles of the convention.

The Council of Europe gave an additional protocol to the Biomedicine convention on genetic testing for health purposes (CETS No. 203, later referred to as the Protocol) in 2008. The general objective is to protect against improper use of genetic tests. Member states to the Council of Europe who have ratified the Biomedicine Convention can ratify this protocol to enforce it in their own jurisdiction.

Under article 2, the Protocol applies to tests, which are carried out for health purposes, involving analysis of biological samples of human origin and aiming specifically to identify genetic characteristics of a person, which are inherited or acquired during early prenatal development. Test fulfilling this definition are called genetic tests in the protocol. Central to the definition is that tests are performed for health purposes. Thus, tests to determine sports genes or other nonmedical conditions are not covered.

Article 5 requires that parties to the Protocol take the necessary measures to ensure that genetic services are of appropriate quality, scientifically and clinically valid, there are quality assurance programme, and persons providing these services have appropriate qualification. Article 6 sets clinical utility as an essential criterion for deciding to offer the test in the first place. Under the explanatory report, the assessment of the clinical utility of the genetic tests shall be assessed on an individual basis, and paying attention to social and cultural aspects. The point is then to consider if the test can guide the person to choose preventive or therapeutic strategies.

As regards the direct-to-consumer (DTCs) genetic tests, the Article 7 of the Genetic testing protocol is central: it sets forth that a genetic test for health purposes may only be performed under individualised medical supervision. This is the basic rule, and exemptions include a test that would not have important implications for the health of person concerned or members of their family or with important implications concerning procreation choices.

The Protocol also establishes an obligation to parties to facilitate access to objective general information on genetic tests, including their nature and the potential implications of their results. The Protocol thus offers an excellent framework to develop criteria and conditions for legislation regarding genetic tests in general, and direct-to-consumer tests in particular (of these DTC tests see later). So far, only five member states have signed the Protocol, Finland representing the only Nordic country, so the protocol is not yet in force. This is a pity,

because the Protocol is thoroughly drafted and reflects considerations of a multidisciplinary expert working group during many years."[250]

14.2 NATIONAL LEVEL

Genetic testing is not regulated in **Poland** and **Serbia**. In Poland, the Minister of Science and Higher Education established a specialized interdisciplinary Panel on the Molecular Genetic Testing and Biobanking who prepared a proposal for the law on genetic tests for medical purposes and published the report in 2012. There have been additional calls for regulation, including a letter from the Ombudsperson urging the head of the government to introduce comprehensive legislation. The 2012 report and the Ombudsman letter outline the need due to: individual rights, discrimination, quality of testing, autonomy & consent, privacy, counseling, and privacy. The 2012 report also calls for the need to consider genetic testing in medical and non-medical uses.

The draft law included in the report lays down in Article 1 that its goal is to establish conditions when genetic tests can be conducted and prevent any forms of discrimination and unequal treatment on the basis of genetic features. In Article 2 point 2.2 the law establishes that it does not apply to genetic testing for research purposes. Noteworthy the law in Article 2 proposes a definition of embryo to be "every human ovum since the moment of fertilization until the end of the eight week of development, as well as any other embryonic totipotent cell".

The law explicitly lays down the prohibition of discrimination on the basis of genetic features (Article 4).

Genetic test may be conducted only after obtaining the consent of the person whom the test directly concerns. (Article 8)

The physician who conducts the test is obliged to provide the patient with information about nature, meaning and the scope of the test. The patient is entitled not to know the results of the test (Article 9).

The proposal contains detailed rules on genetic counselling, which should be provided by a qualified physician (Article 10) and the rules on the storage and destruction of results of the test (Article 12). Specific provisions apply to tests conducted on:

- Minors;
- Incapacitated persons;
- Persons unable to consciously give consent.

Noteworthy, the proposal explicitly prohibits the insurance company from demanding, before and after the signing of the insurance contract, the conduct of genetic tests or the disclosure of results (Article 18). Similar rules apply to employment relations (Article 19).

Similarly in **Serbia**, though no national legislation exists, a conversation has been taking place on the need for legislative protections. However, it is mentioned in article 51 of the *Law on infertility treatment by applying the procedures of biomedically-assisted fertilization* and genetic testing can be requested only by the court (not by employer or insurance

[250] Soini S. Genetic testing legislation in Western Europe—a fluctuating regulatory target. *Journal of Community Genetics*. 2012;3(2):143-153. doi:10.1007/s12687-012-0078-0.

company). This case is defined by article 55 of the *Family Law Act* (Official Gazette of the Republic of Serbia, no 18/2005 and 72/2011).

The Draft Law on the prevention and diagnosis of genetic diseases, genetic anomalies and rare diseases was submitted to the National Assembly of the Republic of Serbia on 3 July, 2014.[251] The provisions of this draft law are related to the testing and analysis carried out in the area of genetic testing in humans, including prenatal genetic testing of the embryo and fetus during fertilization and pregnancy, as well as targeted testing of children and adults with suspected rare diseases. The provisions of this draft law do not apply to multifactorial diseases, genetic tests focused on scientific research, paternity or maternity tests, or the application of genetics in criminal and other legal proceedings.

The draft law provides safeguards against genetic discrimination and stigmatization Legal obligation to communicate genetic research results and ethical guidelines as well as provisions on the "right not to know" are provided by article 21 the same draft of law. The patient undergoing a genetic test is entitled to obtaining full information about their genetic health, in the part where it is the result of testing, and it has to be communicated in a clear and accessible form. The exceptions to paragraph 1 of this Article are:1) The decision of the patient not to be informed about the findings of the test; 2) If the law restricts the exercise of this right for the benefit of the patient or a third party. Only the patient has the right to inspect the result of the genetic testing, or his legal representative when giving consent. The doctor who ordered the analysis has the duty of communicating the result and confidentiality.

Genetic counselling is not required. However, it is recommended for women over 35 years during pregnancy. Genetic counselling team usually consists of medical doctor and geneticist and it can be done in public or private medical practice institution.

The draft law provides the following regulations in article 24: genetic counselling is a mandatory procedure in taking predictive tests, i.e. tests to predict monogenic diseases, detection of genetic predisposition or susceptibility to disease, as well as the identification of persons who can be healthy carriers of the gene responsible for a disease. The method and extent of genetic counselling has to be in line with the expected test result and its implications for the patient examined, especially when it is done to a woman patient, her partner or family member. Genetic advice about conception or birth of a child is communicated in a way that respects the freedom of women in terms of their reproductive behaviour.

Provisions on consent, disclosure, privacy and confidentiality and the issues of genetic testing on minors, incapable persons and those with reduced capacity are regulated by the article 17 of the draft law. Article 23 of the draft law also provides rules on the storage of personal data. The responsible person must keep the results of a person's genetic testing and analysis for a period of 10 years, and at the expiration of this period the data must be immediately removed or erased and physically destroyed. The results of genetic tests can be removed before the expiry of the period referred to in paragraph 1 of this Article, if the patient or their legal representative declares that these results should be removed or if the consent for

[251] National Assembly of the Republic of Serbia, The Draft Law on the prevention and diagnosis of genetic diseases, genetic anomalies and rare diseases; Serbia, of 3 July 2014.
http://www.parlament.gov.rs/upload/archive/files/lat/pdf/predlozi_zakona/2245-14Lat.pdf

genetic testing is revoked. The doctor as the responsible person is required to make a report on the removal of the results of genetic tests.

The introduction of the **German** *Genetic Diagnosis Act* (Gesetz über Genetische Untersuchungen bei Menschen, GenDG)[252] has been preceded by a long and intense discussion.

According to §1 of GenDG "The purpose of this Act is to determine the requirements for genetic examinations and genetic analyses conducted in the framework of genetic examinations and to prevent any discrimination and disadvantage based upon genetic characteristics, especially in regard to the duty of the state to protect human dignity and to ensure the individual right to self-determination via sufficient information".

§2 defines the scope of application: "This Act applies to genetic examinations and genetic analyses conducted within the framework of genetic examinations involving born natural persons as well as embryos and foetuses during pregnancy and the handling of genetic data and genetic samples gained thereby for medical purposes, for purposes of determining descent as well as in the insurance and employment sectors".
The Act does not apply to "genetic examinations and genetic analyses or the handling of genetic samples or genetic data conducted: 1. for research purposes, 2. on the basis of applicable regulations relating to: a) criminal procedure, international legal assistance in criminal matters, the Federal Criminal Authority Act and the police laws of the several states, and b) the Infection Protection Act and the legal progeny of the Infection Protection Act."

Prohibition of a discrimination is referred to in §4 according to which "No one may be discriminated against or disadvantaged on account of his or her genetic characteristics or the genetic of genetically related person in regard to the performance or non-performance of a genetic examination or genetic analysis or in regard to the results of such genetic analysis". Moreover §21 refers to labour law and the prohibition of discrimination included therein. According to this provision "No employer may discriminate against or disadvantage any employee on the basis of his or her genetic characteristics or on the basis of the genetic characteristics of any person genetically related to any employee, especially in regard to the formation of an employment relationship, career advancement, any employment-related instructions or the termination of the employment relationship. The same applies in cases where an employee refuses to allow any genetic examination or analyses to be conducted or refuses the disclosure of the results of any genetic examinations or analyses already performed." Finally the Act refers to the provisions of the General Equal Treatment Act that should apply accordingly (§§15-22).

The Act does not provide oversight to commercial genetic testing.

According to §9 on duty to inform any subject has the right not to have to know the results.

§10 lays down the requirements for genetic counseling, which since 1 February 2012 may only be made by qualified doctors. Not in all cases the counseling is obligatory. The genetic counseling must be made in a generally comprehensible and open-ended form. It should take the form of a personal conversation. It should include a thorough explanation of possible

[252] Genetic Diagnosis Act (Gesetz über genetische Untersuchungen bei Menschen), Germany, 31.07.2009. http://www.gesetze-im-internet.de/bundesrecht/gendg/gesamt.pdf

medical, psychological and social issues, which might arise in relation to (not) conducting the genetic examination as well as the possibilities of support in the case of physical and psychological burdens. In some cases the doctor may recommend genetic counseling of relatives.

The results of a genetic test may only be communicated by the doctor who was responsible for the genetic test or gave the counseling, and only to the person affected. Section 11 (2) permits this information to be given to third parties only with the express consent of the person affected in writing.

GenDG governs data protection with regard to keeping and destruction of the results of the genetic tests and analyses and genetic samples. According to § 12 the results of any genetic examinations and analyses of the subject person must be retained for ten years. Research results must be destroyed if the retention time expires or where the person affected has decided that they should be destroyed. Where the GenDG contains no provision, the general rules on data protection apply.[253] These are set at the federal state as well as at the level of individual Laender.

§14 concerns persons incapable of consenting. In the case of such persons genetic examination is possible only for the direct benefit of the person affected, or exceptionally in order to assess risks in family planning.

Specific provisions relate to prenatal diagnosis (§15) as well as mass screenings (§16). §21 concerns the Labour Law prohibition of discrimination

German Ethical Council issued an opinion entitled "The future of genetic diagnosis". In the opinion the Council refers to the guarantees included in the constitution and puts the primary emphasis on the protection of constitutional law of the person on whose samples genetic diagnosis is carried out.

Genetic Diagnosis Commission (GEKO) is an independent, interdisciplinary commission established at the RKI. It consists of 13 experts from the fields of medicine and biology, 2 experts on law and ethics, as well as 3 representatives of patients, consumers, disabled persons. The role of the Commission is to establish guidelines[254]. So far the Commission has produced a number of guidelines related to individual paragraphs of the act (e.g. genetic counseling, risk, prenatal diagnosis etc.) as well as to monitor the scientific and societal development in the areas of genetics.

In Germany only doctors may provide genetic counselling. According to recent recommendations of the German Ethics Council the experience of other countries should be taken into consideration in order to improve the existing practice.

In **Austria**, genetic testing is regulated by the Genetic Engineering Act.[255] The legislation does not provide for oversight of commercial genetic testing. In order to prevent genetic

[253] In addition the provisions of criminal law on medical confidentiality should be kept in mind.
[254] Genetic Diagnosis Commission (Die Gendiagnostik-Kommission, GEKO)
For more information: http://www.rki.de/DE/Content/Kommissionen/GendiagnostikKommission/GEKO_node.html
[255] Genetic Engineering Act (Gesamte Rechtsvorschrift für Gentechnikgesetz), Austria, 1994.
http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826

discrimination and stigmatization, the law prohibits the use of genetic data for insurance and employment purposes.[256]

The law does not provide for the communication of genetic research results. As research in practice is usually performed in a clinical setting, the provisions on genetic testing for medical purposes are likely to apply. In the clinical setting communication of results is provided under the condition of counselling. Counselling has to be provided for before and after the genetic testing and has to be conducted by a specialist in genetics. Furthermore psychological counselling is offered, but not obligatory. Counselling has to be non-directive and the person concerned has to be informed about the possibility to withdraw previously given consent at any time.[257] The law also provides for recommending to the person concerned to inform family members and include family members in treatment in case there is serious concern that family members are also affected by the same genetic disease.[258] The "right not to know" is not included in the legislation (see also: incidental findings).

Personalized genetic data have to be kept confidential.[259] Appropriate safeguards have to be taken by the respective institution to guarantee confidentiality. The law does however not specify which safeguards are considered as appropriate. The person concerned can at any time demand access to his personal genetic data. Incidental findings have to be communicated to the person concerned in case they are of direct clinical value. Genetic data can only be used for the purpose they were initially collected for. In case there is the intention to use the data otherwise, written informed consent has to be given by the data subject.

Genetic testing of minors, incapable persons and persons with reduced capacity can only be performed after valid consent. Valid consent consists of the consent of the minor depending on his or her capacity to understand the consequences of the testing and of the consent of the guardian. For incapable persons and persons with reduced capacity consent can be given by a representative, in case the person has a representative and the mandate of the representative includes the issue of genetic testing.[260]

In **Spain**, the Law on Biomedical Research devotes Chapter V, Title I and II to regulate the realization of the analyses and does not establish a separation between the guarantees that can be offered when they are done with diagnostic purposes or for research purposes.

The Law regulates the undertaking of genetic analysis and the processing of genetic data of a personal nature exclusively within the health ambit. Genetic analysis shall be undertaken for

[256] § 67, Genetic Engineering Act (Gesamte Rechtsvorschrift für Gentechnikgesetz), Austria, 1994. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826
[257] § 69, Genetic Engineering Act (Gesamte Rechtsvorschrift für Gentechnikgesetz), Austria, 1994. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826
[258] § 70, Genetic Engineering Act (Gesamte Rechtsvorschrift für Gentechnikgesetz), Austria, 1994. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826
[259] § 71, Genetic Engineering Act (Gesamte Rechtsvorschrift für Gentechnikgesetz), Austria, 1994 http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826
[260] § 69(2), Genetic Engineering Act (Gesamte Rechtsvorschrift für Gentechnikgesetz), Austria, 1994 http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826

the identification of an individual's condition as affected, non-affected or as carrier of a genetic variable that could predispose to the development of a specific disease or to condition his response to a specific treatment. In Spain it is forbidden to perform genetic testing for purposes other than those listed above.

Nondiscrimination is regulated in article 6. No one shall be the object of any type of discrimination on account of their genetic characteristics. Also, a person shall not be able to be discriminated on the basis of their refusal to undergo a genetic analysis to provide their consent to participate in a biomedical research or to donate biological material, particularly in relation with the conveyance of medical health care assistance that corresponds to the person.

Article 47 establishes the duty to inform. According to article 26 if research would provide relevant information for the health of the participants, then this must be made available to them, which shall done within the framework of assistance that is underway, or for lack of, by providing a specific counselling.

Besides the provisions emanating from Oviedo Convention, in case of genetic analysis to disabled or minors, the information shall be provided to their tutors or legal representatives.

Article 49 regulates the right to information and right not to know. When the source subject has exercised his right not to know the results of a genetic analysis, then only that information that is necessary for the follow up of a prescribed treatment by the doctor and that has been accepted by the patient shall be provided. When this information, according to the doctor in charge, is necessary to avoid a serious damage for the health of his biological family, then the affected or their legally authorized representative may be informed. In every case, the communication shall be exclusively limited to the data necessary for these ends.

Personal genetic data shall be kept during a period of no less than five years from the date in which they were obtained, after which the interested party may solicit its cancellation.[261]

France has every extensive regulations on genetic testing, where genetic testing is the consideration of the genetic characteristics of a person or his DNA identification.

The provisions relating to genetic testing in general (as healthcare and research procedure) on humans can be found in Chapter III of Title I of Book I of the Civil Code, Title III of Book I of the first part of the legislative part of the PHC, Title III of Book I of the first part of the regulatory part of the PHC and Section 6 of Chapter VI of Title II of Book II of the legislative part of the Penal Code.

Title III of Book I of the first part of the regulatory part of the PHC includes the processing conditions:

- Prescription (Articles R1131-4 and 5 of the PHC)
- Accreditation of Practitioners (Articles R1131-6 12 PHC)

[261] Article 52, Law 14/2007 of 13 July 2007 on biomedical research, Spain, 13.07.2007. http://www.isciii.es/ISCIII/es/contenidos/fd-investigacion/SpanishLawonBiomedicalResearchEnglish.pdf

- Authorization of laboratories (Articles R1131-13 to 18 of the PHC)
- Communication of results (Article R1131-19 PHC)
- Document retention (Article R1131-20 PHC)
- Implementation of information of the kinship (Articles 5 R1131-20-1 PHC).

In addition, the Criminal Code includes criminal provisions punishing attacks on the person resulting from examination of genetic characteristics or identification by genetic prints. According to the Article 16-10 of the Civil Code, examination of the genetic characteristics of a person can be made only for medical purposes or for scientific research.

According to Article 16-13 of the Civil Code, no one can be discriminated against because of their genetic characteristics. According to Article 225-1 of the Criminal Code, what constitutes discrimination is any distinction between natural and legal persons because of, inter alia, their genetic characteristics.

Informed consent is comprehensively addressed.
According to the Article 16-10 of the Civil Code, paragraph 2, the express consent of the person must be obtained in writing prior to the completion of the exam, the person having been duly informed of nature and purpose and purpose of the exam. Consent mentions the purpose of the exam. The consent is revocable at any time.

Therefore no genetic testing (except in the case of court proceedings) can be processed without the express consent of the person concerned. As a consequence, if the person cannot be found or is dead, no genetic testing can be processed on his/her biological samples. This has been a major issue in research projects on biobanks. The Jardé Law creates exceptions to the written consent rules. However, it is not in force yet.

Article L1111-2 of the PHC guarantees every person the right to be informed about their health in general. According to Article R1131-19 of the PHC, the prescriber communicates the results of the examination of genetic characteristics to the person concerned in the context of individual medical consultation. However, according to the same Article, the person can refuse the examination results to be communicated to him/her. In this case, and subject to the provisions of the fourth paragraph of Article L. 1111-2 above, the refusal is documented in the medical record of the person. Furthermore, according to Article L1131-1-2 of the PHC, the person is obliged to inform the members of her/his family potentially concerned or, where applicable, his legal representative has or can obtain the coordinates, if prevention or treatment measures can be offered to them. If the person does not wish to inform him/herself of the potentially affected members of his family, he/she may request in a written document to the prescribing physician, attesting to the request, to proceed with that information. He/she communicates to the physician, for this purpose, coordinates in his/her possession. The doctor then brings to the attention of the family members concerned the existence of a family-oriented medical information that may affect them and invites them to attend a genetics consultation, without disclosing either the name of the person who is the subject of examination, or the genetic defect, or the risks associated with it.
The doctor consulted by the related person is informed by the prescribing physician of the genetic anomaly involved.

In all cases, the decision to disclose to third parties the results of the examination of genetic characteristics remains with the person.

According to the Article L1111-2 of the PHC, the willingness of a person to be kept in ignorance of a diagnosis or prognosis must be respected, except when third parties are at risk of transmission. According to the Article R1131-19 of the PHC, the person may refuse that the results of the examination of genetic characteristics be communicated to him.

Genetic counselling is not required by law but is repeatedly mentioned as a standard procedure. An employer or an insurance company can't require the production of any genetic test (Article 16-10 of the Civil Code). A judge may commission a specific genetic test that is the identification of a person using genetic prints, with the consent of the person tested and as provided by Article 16-11 of the Civil Code.

Genetic testing in the **United Kingdom** is regulated on various levels. Genetic testing for health or research purposes are highly regulated, while there is no direct legislation concerning commercial genetic testing. The United Kingdom did establish a Human Genetic Commission, which developed protocols in its report on regulation Direct-To-Consumer genetic Testing. However, no legislation has emerged.

The definition of genetic testing is addressed in various statues, including:

-Human Tissue and Embryos Bill Human Tissue and Embryos (Draft) Bill
-Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public
-Discrimination Law Review A Framework for Fairness: Proposals for a Single Equality Bill for Great Britain
-Concordat and Moratorium on Genetics and Insurance
-Draft Code of Practice: The use of Personal Data in Employer/Employee Relationships
-Our Inheritance, Our Future: Realising the Potential of Genetics in the NHS
-Code of practice and guidance with respect to genetic paternity testing services
-Laboratory Services for Genetics
-The Human Organ Transplants (Establishment of Relationship) Regulations - Statutory Rule 1998 No.
-Human Tissue Act 2004

There is no single prohibition on "genetic discrimination" but existing laws address the issue, such as which states employers are not allowed to discriminate on the basis of genetic information in employment considerations. Additionally, there is an existing voluntary moratorium (until 2017) in place between the national government and insurers stipulating that genetic tests will not be used as a basis for discrimination for insurance purposes.

15 ISSUES RELATED TO ENVIRONMENTAL IMPACT ASSESSMENT

15.1 EU

Precautionary principle is mentioned in Article 191 of TFEU. According to this principle high level of environmental protection can be achieved through taking appropriate countermeasures, if there are any risks involved. Under paragraph 1 EU environmental policy should be aimed at: preservation and protection of the environment; protection of human health; rational use of national resources, as well as promoting measures at international level, which could resolve environmental problems. Pursuant to paragraph 2, Union policy should

be based on the precautionary principle and the principle of taking preventive actions. It shall also seek to rectify the damage at source and be based on the principle, that the polluter is the one to pay. According to paragraph 3, when preparing its policies in the area of the environment EU should take into consideration: available scientific and technological data; environmental conditions in various regions of the Union; potential costs and benefits of either action or lack of action; economic and social development. Relevant to the issue in question is the Communication from the Commission on the precautionary principle of 02.02.2000[262], according to which the scope of the precautionary principle is much wider and covers not only protection of the environment, but also protection of consumers as well as human, animal or plant health. "*The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk*"[263]. The Commission mentions also criteria concerning measures based on the precautionary principle. They shall be in particular: proportional, non-discriminatory, based on an examination of the potential benefits and costs of action, subject to scientific review, capable of assigning responsibility for producing the scientific evidence[264]. The precautionary principle is also referred to in the judgements of the Court. For instance, according to the judgement of 9 September 2003 Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others "*it follows from the precautionary principle that where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent*"[265].

Of particular importance for the environment protection are two directives: Directive 85/337/EEC on the assessment of the effects of certain public and private projects on the environment (referred to as the EIA Directive)[266] and Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment (also known as the SEA Directive)[267]. The first one has been amended three times (1997, 2003, 2009)[268]. In 2011 Directive 2011/92/EU[269] codified the EIA Directive and its three amendments, however 2014 the new directive has been amended[270] by Directive 2014/52/EU[271].

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[262] European Commission, Communication from the Commission on the precautionary principle, Brussels, 02.02.2000. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52000DC0001&from=PL

[263] Ibid., p. 2.

[264] Ibid., p. 3.

[265] Court, Judgement of the Court of 9 September 2003 Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others, C-236/01, 09.09.2003, para. 111. http://curia.europa.eu/juris/document/document.jsf?text=&docid=48362&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=60977

[266] European Council, Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, Brussels, 27.07.1985. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31985L0337

[267] European Parliament and the Council, Directive 2001/42/EC of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment, Brussels, 27.07.1985. http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32001L0042

[268] European Council, Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment. For more information: http://ec.europa.eu/environment/eia/eia-legalcontext.htm

[269] European Parliament and the Council, Directive 2011/92/EU of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment, Brussels, 13.12.2011. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0092&from=EN

[270] Review of the Environmental Impact Assessment (EIA) Directive. For more information: http://ec.europa.eu/environment/eia/review.htm

[271] Informal consolidated version of EIA Directive can be found here: http://ec.europa.eu/environment/eia/pdf/EIA_Directive_informal.pdf Whenever in this report EIA Directive is mentioned it refers to the consolidated version.

EIA outlines the effects both direct and indirect, which a project will have on the environment when initiated. The term "project" is defined by Article 1 para. 2 letter a of the EIA Directive and it means "*the execution of construction works or of other installations or schemes*" as well as "*other inventions in the natural surroundings and landscape including those involving the extraction of mineral resources*". Article 1 para. 2 letter g lists steps, which shall be taken when conducting EIA:

- preparation of an environmental impact assessment report by the developer;
- consultations;
- examination by the competent authority of the information presented in the environmental impact assessment;
- reasoned conclusion of the competent authority on significant effects of the project on the environment;
- decision regarding consent for carrying out the project.

According to Article 3, effects on the environment should be understood as impacts on the following factors: population and human health, biodiversity, land, soil, water, air, climate, material assets, cultural heritage, landscape as well as the interactions between these factors. There are two types of projects: projects for which EIA is mandatory and project for which it is up to the Member States to decide, whether carry out the assessment or not. The first group is listed in Annex I and includes in particular: crude-oil refineries, thermal power stations and nuclear power stations, whereas the second in Annex II and covers for example surface storage of natural gas, installations for the processing of ferrous materials, ski runs.
According to Article 1 of the SEA Directive "*the objective of this Directive is to provide for a high level of protection of the environment and to contribute to the integration of environmental considerations into the preparation and adoption of plans and programmes with a view to promoting sustainable development, by ensuring that, in accordance with this Directive, an environmental assessment is carried out of certain plans and programmes which are likely to have significant effects on the environment".* SEA should be carried out at an earlier stage than EIA – during the planning phase of the project. Article 2 summarizes the SEA procedure:

- preparation of the environmental report;
- consultations with the public and environmental authorities;
- decision on the plan or programme;
- providing the public and environmental authorities with information on the decision.

SEA Directive does not have lists (comparable to those of EIA Directive) laying down when an assessment is mandatory. However, Article 3 specifies the areas, which are of the essence for the assessments, these are: agriculture, forestry, fisheries, energy, industry, waste management, telecommunications, tourism, town and country planning, land use, which "*set the framework for future developments consent of projects listed in Annexes I and II*" of the EIA Directive. SEA shall also be conducted, when plans or programmes are likely to have adverse effects on the environment under provisions of the Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora[272].

[272] Council, Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, Brussels, 21.05.1992.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31992L0043

15.2 NATIONAL LEVEL

Austria transposed the EU Environmental Impact Assessment Directive[273], Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment,[274]and is signatory to the Convention on Environmental Impact Assessment in a Transboundary Context (Espoo Convention).[275] The environmental assessment act does not mention the precautionary principle as such, but it is the guiding principle on which the act is based. Assessing impact on the environment is also an element of the legislative process and a part of a comprehensive impact assessment. It was introduced in Austria in January 2013 as a key instrument in implementing Better Regulation policies. The precautionary principal is particularly mentioned in relation to GMOs. It is part of the assessment framework of the Advisory Board on biotechnology and genetic engineering.

Impact assessment regarding the environment has been regulated extensively in **German** legislation. The main act concerning that matter is the Environmental Impact Assessment Act[276], which implements in the German legal system the provisions of the Strategic Environmental Assessment Directive (2001/42/EC)[277] and the Council Directive on the assessment of the effects of certain public and private projects on the environment (85/337/EEC)[278]. Germany is also a party to the Espoo Convention. Article 20a of Basic Law stipulates the general rule, under which the state shall establish legislation, which would successfully protect the environment for the future generations. This article is considered to determine obligation for the legislators to implement precautionary principle (Vorsorgeprinzip) to the acts regarding environment. Moreover, in the course of the legislative process, the compatibility of each bill with the criteria of sustainability should be assessed, taking into consideration the protection of environments, economic effectiveness and the social responsibilities.

The most important acts regarding environmental impacts assessments in **Polish** law are:

a. The Act of 3 October 2008 regarding access to information on the environment and its protection, on involving the public in the environment protection and on evaluating impacts on the environment[279];
b. Executive act of 9 November 2010 on undertakings which might significantly affect the environment.[280]

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[273] Environmental Impact Assessment Act (Gesamte Rechtsvorschrift für Umweltverträglichkeitsprüfungsgesetz),Austria, 2000. http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010767

[274] the European Parliament and the Council Directive 2001/42/EC of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment, Brussels, OJ L 175 , 05.07.1985.
http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0042&from=EN

[275] See also: Ministry of Health, Fifth Report of the Commission genetic engineering („Fünfter Bericht der Gentechnikkommission") Austria, 2011, pp. 25.
http://bmg.gv.at/cms/home/attachments/0/7/7/CH1050/CMS1340177484353/5._bericht__gtk_fassung_10.6.11_-_band.pdf

[276] Environmental Impact Assessment Act (Gesetz über die Umweltverträglichkeitsprüfung), Germany, 12.02.1990.
http://www.gesetze-im-internet.de/bundesrecht/uvpg/gesamt.pdf

[277] European Parliament and the Council, Directive 2001/42/EC of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment, Brussels, 27.06.2001.
http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32001L0042

[278] Council of the European Communities, Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, Brussels, 27.06.1985.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31985L0337

[279] Act of 3 October 2008 on access to information on the environment and its protection, on involving the public in the environment protection and on evaluating impacts on the environment (Ustawa z dnia 3 października 2008 r. o udostępnianiu informacji o środowisku i jego ochronie, udziale społeczeństwa w ochronie środowiska oraz o ocenach oddziaływania na środowisko), Poland, 03.10.2008.
http://isap.sejm.gov.pl/DetailsServlet?id=WDU20081991227

According to the provisions, every time the term "impact on the environment" is used, it should be understood also as "impact on public health". Therefore the regulation on environmental assessment applies to public health as well. Moreover, Poland is party to the Espoo Convention. The precautionary principle (*zasada przezorności*, *zasada ostrożności*) has been laid down in the Law on the Protection of the Environment[281]. Under Article 6 paragraph 2, whoever undertakes an activity, whose impacts on the environment have not yet been fully recognized, shall, with all necessary precaution, take all possible countermeasures. This principle is strictly connected with the preventive principle, which has been regulated in Article 6 paragraph 1. According to this principle, whoever undertakes an activity, which might have adverse impacts on the environment, is obliged to prevent those impacts.

The **Serbian** Law on Environmental Impact Assessment[282] implements the two EU directives. Moreover, the Republic of Serbia ratified the Espoo Convention in 2007. The principle of prevention and precaution is highlighted in the Law on Environmental Protection[283] as one of its basic principles. Article 9, paragraph 1, item 2 detailing with this principle, stipulates that every activity must be planned and implemented such that the activity causes minimal possible change in the environment; represents the smallest risk towards the environment and human health; reduces spatial burden and consumption of raw materials and energy in construction, production, distribution and utilization; includes the possibility for recycling; prevents or limits impact to the environment at the source of pollution. The principle of proximity shall be realized through environmental impact assessment and through the use of the best available and accessible technologies, techniques and equipment. The absence of full scientific reliability cannot be the reason for non-performance of measures for the prevention of environmental degradation in case of possible or existent significant impacts to the environment.

In **Spain,** there was some opposition to environmental impact assessment on the grounds that such legislation would hinder businesses competitiveness, but ultimately it was found necessary to take into account environmental factors in the study of projects. European legislation has been transposed through different legal instruments since 1986.[284] Law 21/2013 on Environmental Assessment[285] transposes Directive 2011/92. Article 2 states that environmental assessment procedures must be subject to the principle of precaution, among others.

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[280] Council of Ministers (Rada Ministrów), Executive act of 9 November 2010 on undertakings, which might significantly affect the environment (Rozporządzenie Rady Ministrów z dnia 9 listopada 2010 r. w sprawie przedsięwzięć mogących znacząco oddziaływać na środowisko), Poland, 09.11.2010.
http://isap.sejm.gov.pl/DetailsServlet?id=WDU20102131397

[281] Council of Ministers (Rada Ministrów), Executive act of 9 November 2010 on undertakings, which might significantly affect the environment (Rozporządzenie Rady Ministrów z dnia 9 listopada 2010 r. w sprawie przedsięwzięć mogących znacząco oddziaływać na środowisko), Poland, 09.11.2010.
http://isap.sejm.gov.pl/DetailsServlet?id=WDU20102131397

[282] Law on Environmental Impact Assessment (Zakon o proceni uticaja na životnu sredinu), Official Gazette of the Republic of Serbia, no. 135/2004 and 36/2009, Serbia, 2004.
www.putevi-srbije.rs/strategijapdf/zproczseng.pdf

[283] Law on Environmental Protection (Zakon o zaštiti životne sredine), Official Gazette of the Republic of Serbia, no. 135/2004, 36/2009, 36/2009 –state law, 72/2009 –state law and 43/2011 –Constitutional Court's decision, Serbia.
http://www.putevi-srbije.rs/strategijapdf/zzseng.pdf

[284] Royal Legislative Decree 1302/1986 on Environmental Impact Assessment (already derogated) (Real Decreto Legislativo 1302/1986, de 28 de junio, de evaluación de impacto ambiental), transposed Directive 85/337 of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, Spain, 1986.
http://www.boe.es/buscar/doc.php?id=BOE-A-1986-17240

[285] Law 21/2013 on Environmental Assessment (Ley 21/2013, de 9 de diciembre, de evaluación ambiental) transposes Directive 2011/92 of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment, Spain, 09.12.2013 .
http://www.boe.es/buscar/act.php?id=BOE-A-2013-12913

In **the Netherlands,** almost all national legislation on the environment is incorporated in the Environmental Management Act. Following the EU legislation, the Environmental Act distinguishes Environmental Impact Assessment (EIA) and Strategic Impact Assessment (SEA). In addition to EIA and SEA, it distinguishes two procedures in the Dutch Environmental Act:

- Environmental Impact Assessment for (relatively) simple permit procedure: the simplified procedure.
- Environmental Impact Assessment for complex decisions and SEA for plans and programmes: the full procedure.

The Netherlands Commission for Environmental Assessment is an independent expert body that provides advisory services and capacity development in environmental assessment. It has a legal status to act as an independent advisor since 1987, issuing non-binding advice to government agencies responsible for environmental assessments.

16 CONCLUSIONS

The aim of this deliverable was to identify the legal frameworks that currently guide and/or constrain ethical procedures within research and research assessment in the EU. Partners involved in this task focused on both statutory frameworks and soft-law instruments. They examined the legal and regulatory frameworks at the EU level as well as selected Member States across a defined set of domains, taking account of the international legal environment.

With regard to particular domains that have been identified for the purpose of the task, the following main conclusions may be drawn. A review of national legislation has shown that scientific freedom and the freedom of research, protected under Article 13 of the Charter of Fundamental Rights of the European Union and Article 10 of the European Convention on Human Rights, is either directly addressed by provisions included in Constitutions, or covered by provisions on the freedom of speech (e.g. in the Netherlands). At the same time, it is agreed that other fundamental rights and freedoms may limit scientific freedom, if it is proportionate and justified. For important guidelines on the normative content as well as limits of the freedom one should also look in the jurisprudence of highest national courts. Besides articles on the freedom of research, EU Treaties and the Charter, as well as Constitutions contain a number of other provisions that should have impact on decisions concerning the field of research and innovation, and the ethical procedures within research and research assessment (e.g. provisions that concern the need to protect the environment, sustainable development, animal welfare or public health). While highest legal acts offer crucial guidance in the field of research, at least one fundamental right acknowledged in international treaties (although not directly addressed in the EU treaties, Charter or national Constitutions) and relevant to research remains highly underdeveloped. This is the right to enjoy the benefits of scientific progress and its applications. Currently states pay little, if any attention, to the obligation to recognize and implement this right.

With regard to scientific integrity, rules are typically laid down in soft-law documents that contain also guidelines on how to address scientific misconduct, but rarely touch upon the role of science and researchers in the society, or are concerned with the ethical assessment of research beyond practice-internal research ethics. Many documents are a result of self-regulation of scientific communities.

Only few legally binding demands are put on business to be ethical. In general, companies are not obliged to have a CSR strategy or to have an ethics code or social impact assessment, and activity in this area is voluntary. One exception is the obligation of reporting on non-financial indicators, such as information relating to environment or employment matters, which is a result of the implementation of a EU directive. Only few countries have developed a National Action Plan on Business & Human Rights.

With regard to the processing of personal data for research purposes, the rules are enshrined in laws that implement the EU directive on data processing. The requirements for processing personal data for the purposes of scientific research, as regards the consent of the person whose data is being processed and the need to provide her or him with information, are, in general, less stringent than in other cases and take into account the fact that more demanding obligations imposed on scientists could hinder research or even make it impossible.

There are considerable differences between individual states concerning the development of legislation on biobanking for research purposes. The need to introduce provisions in this area, however, has been widely recognized. Differences exist with regard to the rules on embryo and stem cell research, which remains to be one of the most controversial areas of research.

Issues of impact assessment are regulated with regard to the impact of projects on the environments. Here again national laws are, to a large extent, a result of the introduction of common EU level provisions. Moreover a lot of importance, when it comes to decision concerning the environment, is ascribed to the precautionary principle.

Human subject research is regulated and enforced by a network of systems within each national system. For EU member states, there are varying degrees of implementation of the relevant EU directives, but each are bound by the principles found within the Charter. While comprehensive strategies directly related to human subject research do not exist, the network of guidelines, codes of conduct, and legislation present a series of frameworks with significant overlap of the principles used to guarantee protections and the documents which are most widely cited within the frameworks for their justifications.

The ethical framework for assessing genetic testing in its many varieties is hardly regulated in a few countries and mainly covered as a biomedical device in the countries which do have frameworks for assessing its use. While the Charter prohibits discrimination on the basis of genetic information, there are disparities in what this precisely entails. For those which lack national regulations, there are efforts underway to address, with varied levels of urgency. Each, however, treats this as a developing issue with calls for further development.

The review and further analysis conducted for the purpose of completing the current task have shown that the ethical procedures within research and research assessment are guided by a network of numerous legal acts, some of which do not necessarily explicitly, or solely, concern “research” or “ethics”, as well as soft-law documents, and are shaped by a multitude of actors that either formulate recommendations of general nature for policy makers and/or *de lege ferenda*, or assess individual cases. While in some fields ethical procedures and ethical assessment (e.g. medical research, animal experimentation) are addressed explicitly and function in an environment of a well- established set of rules, in other they are still, especially in the case of some countries, underdeveloped (e.g. non-medical research involving humans). At the same time, noteworthy guidelines on how research should be conducted and the kinds of interests and values that should be borne in mind may be found in the existing statutory

frameworks that provide general rules as well as soft-law documents, especially self-regulation. The task has moreover confirmed that the international and EU laws heavily influence the shape of frameworks and documents, as well as procedures that exist and are being implemented at national level. EU harmonization and international initiatives play a significant role in the establishment of domestic rules and standards concerning research.

PART II: RISK ANALYSIS AND RESEARCH AND INNOVATION IN THE EU LAW: AN OVERVIEW

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SCOPE AND METHODOLOGY

The report has the twofold purpose to provide an overview of risk analysis approaches in European legislation and briefly investigate how research and innovation are taken into account in European policies, with the final scope of giving insights on the relationship and possible impact of risk-based regulation on Research and Innovation.

To this end it takes into account the different types of assessments used in policy actions related to risk analysis and in particular the role of the Precautionary Principle. In this text, risk analysis refers to risks related to environmental, health and safety issues (EHS) and concerns on ethical, legal and societal aspects (ELSA). Other risks relevant for policy action, such as business and financial risks, are not taken into consideration.

The report is structured in three main parts:

- Concept, procedures, structures, areas of application of risk analysis and the references to the precautionary principle in EU primary and secondary legislation
- Policies for research and innovation in EU: definition and approaches, relevant sectors, priorities about risks and ethical and societal concerns
- Cases studies on selected research and innovation areas, relevant both in terms of risk analysis and economical impact at EU level

The analysis is based on the synthesis of publicly available documents, mainly existing literature (secondary sources) and summary of legislations, with specific reference to original legal texts only where relevant to the purpose of the report. The main topics and key words used have been:

- explicit references to rules and obligations related to risk analysis, risk assessment, risk management, impact assessment
- explicit references to the precautionary principle
- explicit references to research and innovation
- key words (main): *risk, risk assessment, risk management, safety, security, precaution, prevention, rights, user rights, impact, impact assessment, ethics, privacy, data protection, integrity, precautionary principle*

Principal sources and "entry point" for document search have been:

- EU-Lex– summary and full texts of EU legislations
- European Commission DGs, in particular: Enteprise and Industry, Environment, Climate Action, Health and Food Safety, Justice and Consumers (JUST), Research and Innovation (RTD), Communications Networks, Content & Technology (CONNECT), Health and Consumers (SANCO)
- OECD Science Policy website
- European Risk Forum website

References to relevant legislations, classified per area, are provided in the annex.

BASIC CONCEPTS

The underlying principle of most of regulatory frameworks worldwide, at least in OECD countries, is that policy actions and measures need to take into account scientific evidence (science-based regulatory decision making). In Europe, this is explicitly recognized by the EU Treaty (TFEU[286], e.g. in art 114).

The so-called risk analysis model is a structured approach to this purpose, originally developed in the U.S. and adopted in the EU since several decades[287]. First legislative references can be found within the food sector in the late 90's[288]. A formal definition for the different risk analyses phases is hereafter reported:

- ***Risk Assessment****: A process of evaluation including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect (s) /event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s). A risk assessment comprises hazard identification, hazard characterisation, and exposure assessment and risk characterisation.*
- ***Risk Management****: The process of weighing policy alternatives in the light of the result of a risk assessment and other relevant evaluation and, if required, selecting and implementing appropriate control options (which should, where appropriate, include monitoring/surveillance).*[289]
- ***Risk Communication****: The interactive exchange of information and science based opinions concerning risk among risk assessors, risk managers, consumers and other actual or potential stakeholders.*

In the last 20 years, the European Commission (EC) has established different structures with the scope of providing scientific advice to the legislator, based on the principle of the best available scientific knowledge. Risk assessment is mainly performed by EC Agencies and Scientific Committees, while risk management is in charge of the EU institutions (Parliament, Council and various Directorate General within the Commission). Risk communication mainly by the EC, but activities might be demanded to agencies and scientific committees.

The EU approach for policy making requires a strict separation between scientific advice (risk assessment phase) and decision-making (risk management phase). The bodies (structures and committees) providing scientific advice to the EC have a mandate based on the principles of independence, competence and transparency, and covering a wide range of risks, products, processes, substances, technologies and production methods. These are[290]:

- EFSA (European Food Safety Authority): Food and feed safety, Animal health and welfare, Plant health

[286] Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union, Brussels, OJ C 326 , 26/10/2012.
http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12012E/TXT&from=EN

[287] Risk analysis and risk regulation serve for a wide range of uses, as well as practical implementation might strongly differ amongst countries. For an in depth analysis see Risk and Regulatory Policy, Improving the Governance of Risk, OECD, 2010

[288] Communication on Consumer health and Food Safety (1997)

[289] A second definition given by the same source is: Decision-making process involving consideration of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyze, and compare regulatory and non-regulatory options and to select and implement the optimal decisions and actions for safety from that hazard

[290] European Commission, Risk assessment and dialogue at EU-level.
http://ec.europa.eu/health/dialogue_collaboration/system/index_en.htm

- EMEA (European Medicines Agency): safety/effectiveness medicines for human use, safety/effectiveness medicinal products for veterinary use, pharmaco-vigilance
- ECHA (European Chemical Agency): Registration and evaluation of chemicals
- ECDC (European Centre for Disease Control and Prevention): Communicable disease, surveillance, preparedness and response
- EEA (European Environment Agency): Air, water, soils pollution, climate change, natural resources and biodiversity
- SCENIHR (Scientific Committee on Emerging or newly identified health risks): new and emerging technologies, such as nanotechnologies, electromagnetic fields (EMF), medical devices, Tissue engineering, etc.
- SCHER (Scientific Committee on Health and Environmental Risks): toxicity and eco-toxicity of chemical, bio-chemical and biological compounds and risks related to biocides, waste, environmental contaminants, water and air quality, endocrine disrupters
- SCCP (Scientific Committee on Consumer Safety): health risks of non-food consumer products, including cosmetics and personal care products, toys, household products, textile and clothing, non chemical risks (mechanical, physical, biological) and consumer services
- SCOE (Scientific Committee on Occupational Exposure Limits): occupational exposure to chemicals

These bodies are in charge of reviewing risk information and data from operators, providing documents that support implementation of risk assessment procedures within legislation, supporting stakeholders' consultation and inform the design of new policies. Assessments from these bodies can be complemented by reports and opinions provided by other EU sources, such as the Joint Research Centre, the Science and Technology Options Assessment (STOA) of the EU Parliament, Member States advisor bodies, expert groups and consultants. At international level, the European Commission has liaisons and agreements with international bodies active on risk analysis issues, such as the WHO, FAO and OECD.

Generally speaking, risk management decisions are taken within European and Member States authorities, following the EU's "comitology" (through committees) process[291]. Depending from the kind of regulatory action, constrains and level of protection required, different elements are taken into consideration. These are both *procedural aspects*, in particular results of risk assessment, stakeholders' consultations, regulatory impact assessment, and *substantive aspects* such as the proportionality and precautionary principles.

A specific regulatory impact assessment (IA) is performed for regulatory decisions (design of new legislation, implementing measures for existing legislation and non legislative initiatives, such as action plans), that are *"expected to have significant direct economic, social or environmental impacts"*. IA aims to provide a comprehensive analysis of data available, enhancing of transparency of the policy process and improving of the overall quality of the regulation. Procedures for IA are defined in the official European Commission IA guidelines (2009)[292].

[291] Details on the EU comitology process are available at:
http://europa.eu/legislation_summaries/glossary/comitology_en.htm
[292] European Commission, the Impact Assessment Guidelines, SEC (2009) 92.
http://ec.europa.eu/smart-regulation/impact/commission_guidelines/commission_guidelines_en.htm

The IA includes assessment of direct and indirect environmental, economic and social impacts, based on existing EU legislations and provisions, in particular the EU Treaty and the Charter of EU Fundamental rights. A full list of impact indicators is provided in the guidelines and related annexes, and all performed impact assessment are listed in the EC website on IA[293].

In Europe a key role in supporting the regulatory process, including risk assessment and management, is played by standards. Regulation 1025/2012 sets out the main principles in order to *"use European standards for products and for services in support of Union legislation and policies, to identify ICT technical specifications and to finance European standardisation"* and defines the role of *European* standardization organization (CEN, CENELEC and ETSI). Standards are voluntary, based on stakeholders' participation and consensus, and focus on supporting development and use of processes and products and thus have a market-driven character.

Harmonized standards are standards that support European legislation[294]. They are developed by EU standard organizations on the basis of a mandate of the EC and are published in the OJEC (Official Journal of the European Communities). Their scope is to provide the technical specifications to address essential requirements of New Approach Directives[295], therefore to protect the public interest, including EHS issues and consumer protection. They can be used to demonstrate that products, services or processes comply with the law (presumption of conformity). In several cases, using harmonized standards compliance with legislation can be based on self-certification. Though Directives refer to harmonized standards, their application remains voluntary. Manufactures are allowed to adopt other technical solutions, besides the one indicated in standards, provided that they are able to demonstrate they meet essential requirements of the legislation. However, certification procedure are more complex and in particular there are no situations where self-certification is allowed.

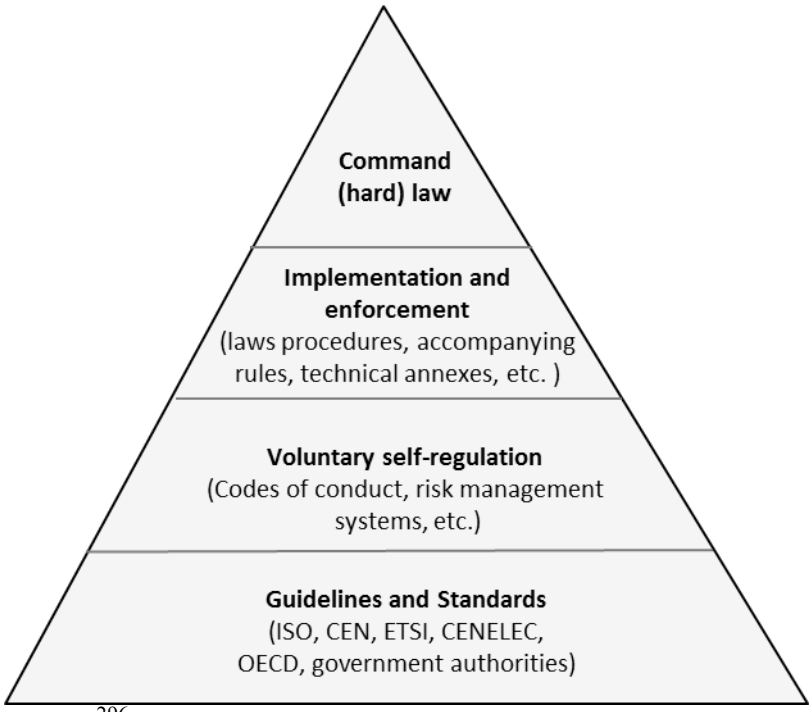
One of the advantages of the new approach is to provide a flexible mechanism to adapt to scientific and technical developments. While essential requirements are laid down in Directives and remain unchanged overtime, harmonized standards can be modified and adapted basing on current technical know-how. This mechanism provides also a powerful tool for competition with other regions in the world, with EU harmonized standards acting as a quality and safety benchmark for companies willing to operate in the EU market.

In conclusion, the regulatory framework that govern technologies is a complex system relying on a number of knowledge building actions, information gathering and dialogue processes instruments, which together contribute to address the risks potentially associated to its development.

[293] European Commission, Impact Assessment.
http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2014_en.htm

[294] A harmonized standard *is "a European standard elaborated on the basis of a request from the European Commission to a recognized European Standards Organization to develop a European standard that provides solutions for compliance with a legal provision."* – See http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm

[295] The new approach has been originally developed in the 80's with the aim to facilitate harmonization of regulatory procedures amongst Member States and free flow of goods (avoid barriers to trade) in the EU market. See: European, Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonization and standards, Brussels, 1985.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:l21001a



The regulatory pyramid ([296])

[296] AIRI elaboration from IRGC reports. See for example "White paper: Risk governance: toward an integrative approach", International Risk Governance Council, 2008.

AREAS AND PROCEDURES FOR RISK ANALYSIS

The final goal of the eu policy and legislative process is to ensure an high level of protection of human health and the environment, preventing and managing risks, while at the same to provide conditions to foster competitiveness and innovation, access to markets and consumers confidence, in a timely and "cost-efficient" manner.

The Treaty recognises as key principles for the functioning of the Union: public health protection (art 168, TFEU); preserving, protecting and improving the quality of the environment (art 191); health, safety and economic interests of consumers (art 169); health and safety of workers (art 153). In particular, the Treaty allows Member States to adopt market and trade restrictions in order to ensure the "*protection of health and life of humans, animals or plants"* (art 36 TFEU)[297]. The rights of EU citizens concerning health protection are further underlined within the Charter of Fundamental Rights of the EU Treaty.

Starting from the TFEU principles (primary law), a wide and complex system of EU and Member States (secondary) laws substantiate the chosen level of protection, integrating scientific requirements and procedures for risk analysis in sector specific areas.

REGULATORY AND ECONOMIC SECTORS

Risk based legislation can be found in plenty of sectors relevant for the EU economy and in particular in virtually all sectors related to manufacturing activities (the most important as far as it regards research and innovation, see next paragraph). A broad distinction of EU risk based laws can be made amongst:

- *Horizontal legislation* (applicable to a wide range of substances, processes, products and sectors): including key laws such as the chemicals regulation (REACH), the worker health and safety protection regulatory framework, the general consumer product safety directive, the product liability directive, most of environmental legislation, in particular the
- *Environmental protection legislation*[298,299]*:* including key laws such as the directives on water, air, waste, pollution prevention and control, control of major-accident hazards, environmental impact assessment
- *Vertical or product/sector legislation*: including key *product oriented* laws such as the medicinal and veterinary products framework, the medical devices directives, the cosmetics directive, the GMOs directives, the biocides and the plant protection products directives; including key *sector oriented* laws in areas such as ICT, transport, climate, energy, construction, etc.

All of these legislations impose a risk assessment and the adoption of risk management measures with respect to health, safety and environmental (EHS) issues. All of these procedures provide examples of different approaches in the application of the prevention principle and the precautionary principle.

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[297] Article 36, Chapter 3 on "Prohibition of quantitative restrictions between Member States", Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union, Brussels, OJ C 326 , 26/10/2012
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT

[298] These legislations require the assessment of environmental risks in the authorization procedures for products, production processes, plants, public and private projects and services, etc.

[299] Overall objectives and principles that underpin future EU policies for the environment are laid down in the Decision no 1386/2013/EU "General Union Environment Action Programme to 2020: Living well, within the limits of our planet. As from article 2 of the decision, key values for EU policy action on environmental protection have to be " the precautionary principle, the principles of preventive action and of rectification of pollution at source and the polluter-pays principle" - http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D1386

However, what it is meant with these terms, and their relationship, varies across these legislations. Several of them explicitly require to perform risk assessment and management procedures. Others require business operators to ensure an adequate level of safety of their products and services, though not referring explicitly to specific risk analysis measure. These legislations impose, at least implicitly, risk evaluation and adoption of appropriate measures for risk control, prevention and mitigation in order to fulfil the general principles set out by the law.

Besides strict EHS issues, EU laws take into consideration also other kind of risks and concerns, related to ethical, legal and social aspects (ELSA), such as security, consumer protection, human rights. Examples of these approaches are provided in the paragraph on the ICT case study in this report.

OVERSIGHT MECHANISM

The EU legislation provides authorities with different oversight mechanisms to review and oversee EHS issues, such as pre-market review and authorization, positive and negative lists, conformity assessments and post-market information and surveillance, setting of limits and targets, and liability schemes.

An indicative, though non exhaustive, list of oversight mechanisms related to risk analysis is hereafter reported, including examples from the different type of legislations mentioned above.

Depending from the legislation, these mechanisms apply to substances, intermediate, processes, products, technologies or a combination of (in the following the generic term "products" is used). The same legislation might refer to some or all of these mechanisms.

Pre market authorization for new products:

Risk assessment is required prior to marketing, including risk-benefit analysis and the development/review of testing procedures specific for the product considered. The required level of information and testing, as well as procedures for registration, evaluation and authorization, vary depending from the sector and the legislation considered.

Generally, the applicant (manufacturer, retailer, importer of the product) has to produce a dossier including information such as: physical and chemical properties and characterization, toxicological and ecotoxicological profiles, exposure routes, guidelines to protect humans, animals and the environment during handling, manufacturing and use of the product.

Upon evaluation and review of the requested information (EU agencies and scientific committees as well as MS), authorization is granted/denied by the competent authority (European Commission, MS or other appointed bodies). Authorization can define specific marketing conditions and provisions for use, be limited to a certain period or time, subject to periodic review and limitations. Once evaluation procedures have been completed, and whenever relevant, products are added to positive or negative lists (see next point).

Examples include: new chemical substances (in particular very high concerns chemicals)[300], workers health and safety[301]; new medicinal for human use (pharmaceuticals), novel foods and feeds, new active agents for food additives, new food contact materials, new active substances for biocides and plant protection products (e.g. pesticides), Genetically Modified Organisms (OGM); the directives on waste, water, Environmental Impact Assessment (EIA)[302].

Pre market authorization for known products (registration/notification):

Positive/negative lists are provided within the legislation and accompanying documents (annexes or guidelines) indicating authorization/prohibition for marketing of that product. Applicants register/notify the product to the authority. Upon evaluation and review of the information, additional risk assessment information may be requested, and finally authorization granted/denied by the competent authority (European Commission, Member States and appointed bodies). Authorization can define specific marketing conditions and provisions for use, be limited to a certain period or time, subject to periodic review and limitations.

Examples include lists for (existing): chemical substances, foods, foods supplements and food contact materials, cosmetics, plant protection products and biocides,.

Conformity procedures (harmonized standards):

Conformity assessment procedures are laid down in New Approach Directives and are mandatory for manufacturers in order to meet EHS and other performance requirements set by these legislations. Manufacturers need to carry out a risk analysis to determine the essential requirement applicable to the product, including the level of risk and the applicable directives for the conformity assessment. The assessment tasks are organized in modules, covering different phases along the product value chain, depending from the product and directive considered. Harmonized standards can give a presumption of conformity with respect to modules requirements (e.g. the EN ISO 9000 standards series can be used to comply with the production quality assurance basic module).

The procedure includes preparing a technical file, a declaration of conformity and affixing the CE marking. The technical file details how the products meets the Directive requirements and must include the product design characteristics, reference to standards, information regarding

[300] The REACH regulation include different levels of risk analysis depending from the type of substance considered. Authorization of chemicals of very high concern require the manufacturer to develop a detailed risk assessment. In order to inform the decision making process on the substance, the European Commission requires an opinion to the REACH Risk Assessment Committee (REC), open for public consultation for a certain period of time, and perform a Socio-economic Analysis (SEA) on socio-economical impacts. The final decision takes into account a detailed risks, benefit and costs analysis. See http://echa.europa.eu/regulations/reach/restrictions/restriction-procedure

[301] European Commission, Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work - "Framework Directive", on occupational health and safety requires employers to carry out an assessment of the risks to safety and health at work, including aspects such as hazard identification, worker participation, measures to eliminate or prevent risk at source, periodical re-assessment of workplace hazards.
https://osha.europa.eu/en/legislation/directives/the-osh-framework-directive

[302] The EIA Directive (2011/92/EU) is related to the assessment of the environmental effects of public and private projects which are likely to have significant effects on the environment. A detailed EIA report need to to be produced including data such as (annex IV): use of materials and natural resources (water, land, soil, energy, etc), expected residues and emissions, likely significant effects of the project compared to the existing scenario, risks to human health and the environment, impact on climate, etc

the systematic risk assessment performed, technical and safety measures for the appropriate use of the product.

Depending on the level of risks, products can be self-certified by the manufacturer or might need review and testing by a notified body. Notified bodies are independent testing companies authorized by the EU member states to perform the conformity assessment tasks specified in directives.

Examples include directives related to[303]*:* medical devices, electrical goods, electronics, toys and other consumer products, consumers and workers protection, appliances, machinery, transport (vehicles), construction, energy and other product families.

Post market surveillance and information:

Market surveillance is an essential aspect of risk management activities in charge of EU and MS authorities. There is a wide range of tools in place that allow authorities to monitor, evaluate and, if a particular risk is identified, restrict the use of a product on the market (or withdraw it). These include health monitoring and vigilance measures, market controls, early warning systems, re-assessment of existing data from authorities (based on new knowledge available) and requests for risk assessments updates to applicants.

Other tools are meant to support exchange of information, including mechanisms such as hazard classification, traceability and labelling of products. They have a twofold purpose: help authorities to gather information and monitor type and conditions of use of products; inform players along the value chain, including final users and consumers, on characteristics, possible risks and safety measures of products; support the adoption of adequate preventive and precautionary measures.

Examples of different procedures in EU legislation are:

- The Regulation (EC) No 1272/2008 **on** regulation on classification, packaging and labelling (CLP) of chemicals, complementing Regulation (EC) No 1907/2006 on chemicals (REACH), sets out mandatory rules for the classification of chemicals according to their hazardous properties, and require indications (on packaging) such as substance composition, hazard category and precautionary measures for the handling and use of the substance. Classification refer to the international standard set by the United Nations Globally Harmonized System (GHS).
- The directive 2012/18/EU on control of major-accident hazards, covering thousands of industrial installation in EU (mainly chemicals), require companies handling relevant amounts of dangerous substances to set up early warning and surveillance procedures for these substances, such as: provide authorities with vigilance, safety and prevention policies, realize and maintain information systems for people that may be affected by major accidents[304], to provide an updated and detailed safety report on the installation.

[303] A list of EU harmonised standards and related legislative acts is available at http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm

[304] In accordance with the principles set out in the "Convention of the United Nations Economic Commission for Europe on access to information, public participation in decision-making and access to justice in environmental matters (the Aarhus Convention). http://ec.europa.eu/environment/aarhus/

— The legislative framework for GMOs[305] require to identify any product *"which consist of GMOs or which contain them"*, with a code (unique identifier) that have to be part of the labeling of GMOs products. The code ensure traceability along all stages of production and placing, and allows authorities to restrict or withdraw products from the market in cases of identified EHS risks.
— The directives regulating medical devices establish the European databank on medical devices (Eudamed), a repository including data on manufacturers, authorized devices, related certifications, vigilance reports, and clinical investigation data. The repository is available only to EC and Member States authorities, but an going revision of the legislation is planning to further improve in the traceability and transparency on medical devices on the market[306].

Setting of emission limits, thresholds, priority lists, type-approval and performance targets:

These are standard risk management procedures applied to substances, products and production processes in several legislations to limit or discourage the use of certain substances, monitor and control critical EHS parameters of products (thus preventing hazards), improve EHS performances in specific sectors, define liability regimes. The chemical, environmental, energy and transport related legislations make large use of these procedures.

Examples include:
— The Regulation (EC) No 1907/2006 on chemicals (REACH) is using threshold values (annual volumes of substances manufactured or imported per year) to define applicable risk assessment and management measures. For example, for substances manufactured/imported above 10 tonnes a full chemical safety assessment report (instead of a simpler substance dossier) is requested.
— The health and safety at work framework (Directive 89/391/EEC and related acts) defines binding occupational exposure limit and biological values for chemical agents for the protection of workers from chemical risks
— The water protection and management framework and related acts (e.g Directive 2013/39/EU) define a list of priority hazardous substances and sets out Environmental Quality Standards (e.g. max concentrations in different environments) for reference within water policies and legislations and other acts (e.g. for evaluation of substances within REACH)[307].
— The Directive 2010/75/EU on industrial emission (concerning industrial installations in the energy, chemical, mineral and other sectors) include limits related to air, water, soil and waste with respect to activities with high pollution potential[308].

[305] See in particular: The European Parliament and of the Council, Regulation (EC) no 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.
[306] See: Revision of the medical device directives.
http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm
[307] Priority lists follows as results of detailed risk assessments on each of the substances, including ecotoxicological and toxicological effects, monitoring of concentrations in the environment, etc. See in particular Directive 2013/39/EU on priority substances in the field of water policy
[308] The European Parliament and of the Council, Directive 2010/75/EU on industrial emissions (replacing former IPPC-Integrated Pollution and Prevention Control directive) does not refer explictly to risk assessment, but to the use of Best Available Techniques (BAT) that need to be adopted by operators to achieve the requested level of protection of the environment (BAT, including emission limits, are defined by the European Commission) as well as to procedures for *"systematic appraisal of the environmental risks"*.

— The Regulation (EC) No 661/2009 on general safety of motor vehicles, and related acts, sets so-called *"type-approval"* procedures, defining type of vehicles that are allowed to be marketed based on mandatory emission and noise limits (e.g. the "Euro 5 and 6" series) as well as installation of safety equipment. Several acts have been published in the last years and the regulation is expected to evolve over time, following comprehensive impact assessment of regulatory action by the EC and MS[309].
— Various legislations related to energy efficiency[310] set minimum requirements and benchmarks for energy performances of specific products. Feasibility study, technical and conformity assessments might be required depending from the product considered. Examples include the directive on Energy performance of buildings and the regulation on ecodesign rules applicable to certain types of lamps for general lighting.

Liability schemes

These are legislations defining frameworks for liability with respect to preventing or restoring damages to people or the environment related to specific products and areas. In case of claims, risk analysis procedures are essential to evaluate and define liability[311]. Therefore, besides supporting people to claim for the failure of a product, or to damages related to environmental accidents, these legislations foster business operators to adopt a precautionary approach. Key examples include the product liability directive (**Directive 1999/34/EC)** and the environmental liability directive (**Directive 2004/35/CE)**.

[309] See: The European Parliament and of the Council, Regulation (EC) No 661/2009 of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor, Brussels, 2009.
http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32009R0661&from=EN

[310] Overall objectives and principles that underpin future EU policies for the environment are laid down in the EU Communication Energy Efficiency Plan 2011 -COM(2011) 109.

[311] For example, the product liability directive states (article 7): *The producer shall not be liable as a result of this Directive if he proves: [..] that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.*

THE PRECAUTIONARY PRINCIPLE

Emerging in European environmental policies in the late 1970s, the precautionary principle (PP) is now enshrined in various international treaties and declarations.

The first endorsement of the principle at international level was in 1982 when the World Charter for Nature was adopted by the United Nations General Assembly, while its first international implementation was in 1987 through the Montreal Protocol on climate change[312]. Soon after, the principle was integrated with other international treaties such as the Rio Declaration and Kyoto Protocol, cornerstones for its wide dissemination[313].

In its "strongest" formulations, the principle can be interpreted as demanding absolute evidence of safety prior to taking action (e.g. allowing new technologies to be adopted). The World Charter for Nature (1982) provides an example of this kind of formulation, stating that *"where potential adverse effects are not fully understood, the activities should not proceed."*

Regulation is advocated any time there are strong doubts about a possible risk to health, safety, or the environment, even if the economic costs of regulation are high.

Other "weaker" formulations suggest the introduction of cost-benefit analysis and judgment procedures, such as the globally acknowledged definition resulting from the work of the Rio Conference, stating (Principle #15 of the Rio Declaration):

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Besides environment and climate, other key areas of application of the PP include foods and GMOs. Key international agreements include the WTO Agreement on Sanitary and Phytosanitary Measures[314] (providing guidelines on risk assessment and precautionary measures on food safety, animal and plant health) and the Cartagena Protocol on Biosafety on the safe transfer, handling and use of GMOs [315].

The PP has been formally introduced in the EU Treaty in 1992, in relationship with environmental protection (in TFEU, art 191)[316]. The EU Treaty does not provide any formal definition or procedures for implementation, which are left to secondary legislative acts and Court decisions.

The PP, together with the prevention principle (in TFEU, article 191, 192), provides two basic references for risk analyses in the EU law. Though both are prescribed in the EU Treaty in relationship with the environment, their scope is wider, with an impact in numerous EU laws regarding environment, human, animal and plant health protection.

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[312] The *"Montreal Protocol on Substances that Deplete the Ozone Layer"* is an international Treaty that came into force in 1989, aiming to protect the ozone layer by phasing out the production of numerous substances that are responsible for ozone depletion. The document is available at http://ozone.unep.org/pdfs/Montreal-Protocol2000.pdf

[313] Rio Declaration on Environment and Development, Report of The United Nations Conference on Environment and Development, available at http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm

[314] The WTO Agreement on Sanitary and Phytosanitary Measures is available at http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm

[315] The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is available at https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf

[316] Art 191 TFEU: "Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay." Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union, Brussels, OJ C 326, 26/10/2012.

The prevention principle applies where risk can be calculated/quantified on the basis of scientific knowledge, and require to define preventive actions to reduce or avoid the risk. Definition of “acceptable risks” is science based. As briefly shown in the previous paragraph, several EU legislations include requirements to take risk preventive measures.

The precautionary principle is used in situation of scientific uncertainty where risks can not be predicted clearly, and precautionary actions might be taken to reduce the risk. Definition of “acceptable risks” include considerations related to both science and societal factors. The concept of precaution within the PP can be considered as "*caution in advance*" or "*caution practised in the context of uncertainty*".

The EU approach to the PP is outlined in the European Commission communication on the precautionary principle adopted in February 2000. The text follows the White Paper on Food Safety (January 2000) and the Cartagena Protocol on Biosafety.

In this document, the Commission sets out the specific cases where the application of the PP principle can be pursued:

1. *where the scientific data are insufficient, inconclusive or uncertain;*
2. *where a preliminary scientific evaluation shows that potentially dangerous effects for the environment and human, animal or plant health can reasonably be feared.*

The key actions needed to decide how to apply the PP include:

1. *a complete scientific evaluation carried out by an independent authority in order to determine the degree of scientific uncertainty;*
2. *an assessment of the potential risks and the consequences of inaction;*
3. *the participation, under conditions of maximum transparency, of all the interested parties in the study of possible precautionary measures.*

The PP is considered a risk management option, in charge of decision making authorities. Measures resulting from recourse to the PP may include both regulatory and non regulatory actions (e.g. developing new scientific knowledge), depending on the level of risk considered "acceptable".

After the adoption of the EC Communication on the PP, the principle has come to inform much EU policy, including areas beyond environmental policy. Typically concerned by the PP are:

- Public health
- Food safety
- Environment
- Climate change, global warming
- Biodiversity, extinction of species
- High concern chemicals
- Emerging technologies (biotech, nanotech and others)

A telling example of application of the PP in Europe is the adoption of a moratorium on commercialization of GMOs between 1999 and 2004.

Despite a growing body of case law, including important decisions by the (European) Court of Justice, the legal community remains divided about the meaning and applicability of the principle.

APPLICATION IN THE EU LEGISLATION

The Precautionary Principle provides a normative reference to identify and provide precautionary approaches to risks in all (risk based) legislation in Europe. However, only few regulations and directives explicitly mention it. Examples are:

Environment and Pesticides

The precautionary principle is underpinning EU policy action on environment, as clearly acknowledged in both the previous and current Community Environment Action Programme (EAP). Article 2 of the 7th EAP states that[317] *"The 7th EAP shall be based on the precautionary principle, the principles of preventive action and of rectification of pollution at source and the polluter-pays principle"*.
In particular, the programme invoke the application of a precautionary approach for substances and products covered by the legislations on chemicals (REACH), biocidal products and plant production products for which there is still uncertainty on EHS issues[318].

The PP is explicitly mentioned in the Directive 2009/128/EC on the sustainable use of pesticide**,** which envisage a precautionary and preventive approaches in legislative actions at Member States level and allows Member States to *"apply the precautionary principle to restrict or prohibit the use of pesticides in specific circumstances or areas"*.

Regulation 1107/2009 regarding the placing of plant protection products on the market contains a reference to the PP (art.1):
"*The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.*"

Several other environmental legislation have been drafted taking into account the PP and might include specific reference to a precautionary approach. Examples include the directives on waste (in particular waste incineration), industrial emission (in particular to determine the "Best Available Technique" for risk prevention), air quality (to determine priority hazardous substances).

Food and Feed

Regulation (EC) No 178/2002 sets out common principles and responsibilities for the safety of food and feed in Europe, aiming to a high level of protection of human, animal, plant health, and the environment. Risk analysis is an integral part of the regulation (article 6) and the article 7 is devoted to precautionary principle, stating: *In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.* Following indications given by the EC PP communication, the food law require these

[317] The European Parliament and the Council, Decision no 1386/2013/EU of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet', Brussels, 2013. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32013D1386

[318] Very high concern substances, endocrine disruptors, chemicals in products, mixtures, nano materials are mentioned. See priority 3 (50) of Decision No 1386/2013/EU

measures to be reviewed *"within a reasonable period of time"*.

Genetically Modified Organisms (GMOs)

The release into the environment and the marketing of GMOs in the EU is mainly regulated by the general provisions of Directive 2001/18 and Regulation 1829/2003, and various other laws (see case studies paragraph).

The PP is part of the scope of the directive, and it has been also taken into account in the drafting of the various pieces of legislations related to traceability, labelling, and transboundary movements of GMOs. Directive 2001/18 states: "*Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs"*.

The Regulation (EC) No 1946/2003 on trans boundary movements of GMOs, refer to the precautionary approach provided in the Cartagena Protocol on Biosafety (2000).

Consumer products (toys)

An example of stringent risk based legislation on consumer products is the Directive 2009/48/EC on the safety of toys, providing authorization procedures and safety requirements for toys produced and imported in the EU market. The PP is included in the preamble of the directive (with reference to the EC communication on the PP), which states *"Where the available scientific evidence is insufficient to allow an accurate risk assessment, Member States, when taking measures under this Directive, should apply the precautionary principle"*. The application of the PP is envisaged for market surveillance activities, for the use of chemical substances in toys (reference is given to REACH) and for specific risks related to toys in foods.

Chemicals

The manufacturing, placing on the market and use of chemical substances on their own, in preparations or in articles is covered by Regulation (EC) No 1907/2006 (REACH - Registration, Evaluation, Authorization and Restriction of Chemicals), entered into force in 2007. REACH is considered one of the most stringent and precautionary regulations on chemicals worldwide. The two main differences with other legislations (e.g. in the U.S.) are related to the inclusion of the PP within the objective of the regulation and the fact that the burden of proof is given to the manufacturer. This is declared in the aim and scope of REACH (article 1): "*This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle."*

EU POLICIES FOR RESEARCH AND INNOVATION

The EU Treaty emphasize the role and importance of research and technological development, as well as its cross cutting character across different area and sectors of EU policy. A chapter of the Treaty is devoted to *"research and technological development and space"* and envisages the creation of a "*European research area in which researchers, scientific knowledge and technology circulate freely"* and to promote *"all the research activities deemed necessary by virtue of other Chapters of the Treaties"*. The Treaty require to the Union to adopt multiannual framework programmes to define and support scientific and technological objectives and priorities for Europe.

The EU 2020 strategy[319], which provides the vision for the design of the latest framework programme on R&I (Horizon 2020), is geared around the three pillars of smart, sustainable and inclusive growth and promoted eight flagship initiatives along these pillars.

The 'Innovation Union' flagship is the one devoted to define a strategic and integrated approach to research and innovation. Activities of Innovation Union are complemented by the other flagship initiatives. The most relevant in terms of promoting R&I and translating its results into products, processes and services are:

- *Digital Agenda for Europe*, to promote deployment of ICT
- *Resource-efficient Europe*, supporting policy agendas for climate change, energy, transport, industry, raw materials, agriculture, fisheries, biodiversity and regional development
- *An industrial policy for the globalization era*, aiming to support a *"strong, diversified and competitive"* Industrial base in Europe. It includes six action lines: sustainable industrial policy, construction and raw materials, clean vehicles and vessels, bio-based products and markets, smart grids, advanced manufacturing technologies, Key Enabling Technologies

The Framework Programme for Research and Innovation (2014-2020) ("Horizon 2020") is the main legislative instrument for R&I to realize the objectives of the EU 2020 strategy for R&I, together with measures and funding provided by Member States within the European Structural and Investment Fund (Smart Specialization Strategy), as well as the Competitiveness and Innovation Framework Programme (COSME)[320].

Defining Research and Innovation:

Research, Research and Experimental Development (R&D) and Research and Innovation (R&I) are broad and general concepts, applicable to different context, organizations and activities. Acknowledged definitions for policy analysis are given by the OECD Frascati[321] and OECD Oslo manuals[322].

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[319] Europe 2020: A strategy for smart, sustainable and inclusive growth (COM(2010) 2020 final of 3.3.2010)

[320] A full list of EU funding instruments for R&I and competitiveness, and synergies amongst the different tools, is available in "Enabling synergies between European Structural and Investment Funds, Horizon 2020 and other research, innovation and competitiveness-related Union programmes", European Commission, 2014 - http://ec.europa.eu/regional_policy/sources/docgener/guides/synergy/synergies_en.pdf

[321] Frascati Manual, available at http://www.oecd.org/science/inno/oslomanualguidelinesforcollectingandinterpretinginnovationdata3rdedition.htm

[322] OECD, Oslo Manual, 2005. http://www.oecd.org/science/inno/2367580.pdf

From a normative point of view, a definition is given in the article 2 of the Horizon 2020: *"research and innovation activities mean the whole spectrum of activities of research, technological development, demonstration and innovation, including the promotion of cooperation with third countries and international organisations, the dissemination and optimisation of results and the stimulation of high quality training and mobility of researchers in the Union"*.

A broad meaning is given to the term "innovation" that, as stated for example in article 15, includes *"business, organisational, technological, societal and environmental aspects"*.

For the first time, Horizon 2020 merged the concepts of research, technological development and innovation together and started to use a formal definition for research and innovation. Its worth noting that in previous framework programmes the term "research and innovation" itself was not defined. The EU Lisbon Strategy mentioned separately research and development (RTD) and innovation, the Seventh Framework Programme (FP7) programme was about *"research, technological development and demonstration activities"*[323].

The main scope of this change in H2020 has been to emphasise the need to foster and increase the exploitation of research and technology and their deployment into innovative products and processes (shorten the path from the laboratory to the market). Likely more than in the past, the impact of research activities in industry, business as well as society is becoming a key aspect in the definition of research (and innovation) policies and legislations in Europe.

TECHNOLOGY AND ECONOMICAL AREAS

Regulation N. 1291/2013 ("Horizon 2020") determining the framework governing the Union support to research and innovation, rests on three pillars:

- Excellence in science: Future Emerging Technologies[324],
- Leadership in Industrial Technologies: Key Enabling Technologies [325]
- Tackle societal challenges[326]

These objectives provides a clear view about the most relevant technological and economical areas for research and innovation in Europe. From a technological point of view, in the short to medium term these are the Key Enabling Technologies[327], on the long term also Future Emerging Technologies are expected to play a role. From a socio-economical perspective, these are mainly the areas identified by H2020 societal challenges and by the flagship initiatives (healthcare, food, agriculture and the bioeconomy, energy and renewable energy,

[323] The EU Seventh Framework Programme for Research and Innovation. http://eur-lex.europa.eu/resource.html?uri=cellar:fea6bf93-6db4-473b-b40c-acf92978d6e1.0005.02/DOC_1&format=PDF

[324] FET includes: early-stage (novel) science and technology research: promising exploratory research themes (including domains such as cognitive sciences, robotics, cyber-physical systems, quantum technologies, high-performance computing); FET flagship on graphene and the human brain project

[325] KETs are: Photonics and micro-nanolectronics (ICT), Advanced materials, Biotechnology, Nanotechnologies, Advanced manufacturing systems

[326] 1) Health, demographic change and well-being; 2) Food security (sustainable agriculture and forestry, marine, maritime and inland water research, and the bioeconomy); 3) Secure, clean and efficient energy; 4) Smart, green and integrated transport; 5) Climate action, environment, resource efficiency and raw materials; 6) Europe in a changing world: inclusive, innovative and reflective societies; 7) Secure societies: protecting freedom and security of Europe and its citizens).

[327] H2020, pg. 133: *"An integrated approach, promoting the combination, convergence and cross-fertilization effect of KETs in different innovation cycles and value chains can deliver promising research results and open the way to new industrial technologies, products, services and novel applications (e.g. in space, transport, agriculture, fisheries, forestry, environment, food, health and energy)"*.

transports, climate and the environment, constructions, materials, use of resources and advanced production processes, security, and humanities)

A complementary source of reference on relevant areas for R&I in Europe is given by R&D indicators (patents and publications from European organizations). From the Innovation Union Competitiveness Report[328], key areas (technological and economical fields) of specialization in science and technology include: *ICT, materials, health, new production technologies (machinery and equipment), environment, green energy, biotechnology, security, automobiles and other transports, food, agriculture and fishery, energy, construction and construction technologies, nanotechnology, aeronautics and space and humanities.*
ICT, materials, health are amongst the most relevant in terms of both patents and publications.

RISKS, ETHICAL AND SOCIETAL IMPACTS

Risk based regulation, as discussed in the previous paragraph, focuses on specific areas (sectors, technologies, and products, processes) to address related EHS issues and ELSA. Besides the laws specifically addressing research activities on humans and animals[329] and few other cases[330], these legislations do not (generally) include specific requirement or distinction regarding the different phases of the research, technological development and innovation process.

However, **all legislation and normative actions regulating the technology and economical/market areas described in the previous paragraph have a direct and relevant impact on R&I activities** carried out by industry, research institutions and other organizations.

These legislations can act both as a *constrain* and a *driver* for R&I players in order to design processes and products suitable for the EU market: legislations set limits to prevent and manage risks and concerns of R&I products, requires actions to address ethical and societal challenges of R&I products, and define targets for the improvement of performances of R&I products.

A brief analysis of the Horizon 2020 regulation and the EC communications on the flagship initiatives, based on the key words given in the methodology section, provides an overview of priorities and key areas regarding risks, ethical and societal concerns of R&I.

Though these policy documents mainly refer to R&I performed with public funding (EC and Member States), they represent a main reference for all organizations undertaking R&I at European level as well as for regulators to develop sector specific regulations (e.g. the Digital Agenda required to start the ongoing discussion about the recast of the e-privacy directive).

The issues of **risk assessment and management and health, safety and environmental impacts** are explicitly mentioned in the following areas with reference to the different pillars:

[328] European Commission; Innovation Union Competitiveness Report 2011.
http://ec.europa.eu/research/innovation-union/index_en.cfm?pg=home&section=competitiveness-report&year=2011
[329] These mainly refer to the legal frameworks related to: medicinal products for human use, and in particular the clinical trial directive 2001/20/EC and, since 2016, the Regulation EU No 536/2014; medicinal products for veterinary use, in particular the Directive 2001/82/EC; animal testing, in particular Directive 2010/63/EU.
[330] In some legislations there are exemptions related to substances intended for research purposes, mainly related to the limited quantities of substances generally used in the laboratory. Examples are in the Regulation (EC) No 1907/2006 on chemical (REACH) and in the Directive 2010/75/EU on industrial emissions.

Pillar on Industrial Leadership:

- **ICT**: an overall objective of the action is that R&I of ICT systems shall respect the fundamental rights and freedoms of natural persons, in particular the right to privacy.
- **Nanotechnologies**: research lines are foreseen to provide tools for risk assessment and management along the entire life cycle of products and applications and for work on standardisation and safety.
- **Biotechnologies**: an overall objective of the action is to integrate in R&I activities the health and safety assessment, the economic and environmental impact of use of the technology and the management aspects of the overall and specific risks of biotechnologies.
- **Materials**: an overall objective of the action is to consider for R&I activities a full life-cycle approach, and to minimize the use of resources and negative impacts for humans and the environment.
- **Advanced manufacturing**: research line on sustainable construction technologies and systems (resource and energy efficient systems and buildings) to reduce environmental impact; research line on process manufacturing industries to improve sustainability, resource and energy efficiency, use of renewable energy sources and reduction of environmental impacts.

Pillar on Societal Challenges:

- **Secure, clean and efficient energy**: research line on the development of tools and methods for environmental impact and sustainability assessment.
- **Smart, green, transport/ resource efficient transport**: overall objective of the action for R&I activities in these areas to enable substantial reduction in greenhouse gases, dependence on fossil fuels, and other adverse environmental impacts as well to ensure safety and security of transportation systems.
- **Climate** (environment, resource efficiency and raw materials): overall objective of the action is to reduce (natural) resource use and environmental impacts. Research line on sustainable supply of non-energy and non-agricultural raw materials; research line on eco-innovative technologies, processes, services and products, including exploring ways to reduce the quantities of raw materials in production and consumption; research lines to develop *"cost-effective adaptation and risk prevention and management measures"* in fighting and adapting to climate change.
- **Food and agrifood**: an overall objective of the action is to foster *"an optimal and renewable use of biological resources and towards sustainable primary production and processing systems that can produce more food, fibre and other bio-based products with minimized inputs, environmental impact and greenhouse gas emissions, enhanced ecosystem services, zero-waste and adequate societal value."*
- **Secure Societies**
  - security threats**:** overall objective of the action for R&I to support *"understanding, detecting, preventing, deterring, preparing and protecting against security threats"* (with respect to to human rights, environmental

degradation, political stability and democracy, social issues, cultural and religious identity or migration, etc.).

- cyber security, trust and privacy in the EU digital market: an overall objective is to develop technologies and solutions that address security gaps and lead to a reduction in the risks from security threats. Attention to abuse of privacy and breaches of human rights in the internet, and functioning of critical ICT infrastructures. Research lines are foreseen to "*ensure privacy and freedom and enhance the societal legal and ethical understanding of all areas of security, risk and management"*.

— **Inclusive, innovative and reflective society**: an overall objective is to foster research in social science and humanities to tackle EU major socio-economical challenges. Impacts of innovation, in areas such as ageing and demographic change, ICT (digital divide), sustainability and employment are considered. One of the focus of the activities is to understand, foster and implement *"Europe's role as a global actor, notably regarding human rights and global justice"*.

Some articles of Horizon 2020 are devoted to **ethics and ethical impacts of R&I**, and concern policy and research objectives of all the H2020 regulation. They reflect some of the EU pillars for responsible research and innovation, including gender equality (art 16), researchers' careers (art 17), open access (art 18), and respect of ethical principles (art 19). References are given to article 13 TFEU and article 168 TFEU. In particular, article 19 main provisions are:

— *All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.*
Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.
— *Research and innovation activities carried out under Horizon 2020 shall have an exclusive focus on civil applications.*
— *The following fields of research shall not be financed:*
  - *research activity aiming at human cloning for reproductive purposes;*
  - *research activity intended to modify the genetic heritage of human beings which could make such changes heritable;*
  - *research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.*
— *4. Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden.*

Strict limits in relation to research in human stem cells are reiterated in the introductory text of the H2020 legislation[331]. Procedures for ethical review by the European Commission are defined in regulation (EU) No 1290/2013, setting rules for participation in H2020 (article 14 on ethics review).

With respect to the above mentioned aspects, the key agency that provides technical and scientific advices and perform impact assessment on H2020 policies, is the Joint Research Council (JRC). Regarding ethical aspects, the opinions of the European Group on Ethics in Science and New Technologies are considered.

H2020 refer to the European Charter for Researchers[332], a set of general principles and requirements which specifies the roles, responsibilities and entitlements of researchers as well as of employers and/or funders of researchers.

[331] Page 107: *The Commission does not explicitly solicit the use of human embryonic stem cells. The use, if any, of human stem cells, be they adult or embryonic, depends on the judgment of the scientists in view of the objectives they want to achieve and is subject to stringent ethics review. No project involving the use of human embryonic stem cells should be funded that does not obtain the necessary approvals from the Member States. No activity should be funded that is forbidden in all Member States. No activity should be funded in a Member State where such activity is forbidden.*

[332] European Commission, the European Charter for Researchers.
http://ec.europa.eu/euraxess/pdf/brochure_rights/am509774CEE_EN_E4.pdf

CASE STUDIES
INFORMATION AND COMMUNICATION TECHNOLOGIES

The Information and Communication Technologies (ICT) are related to networks, systems, software and devices that enable users to access, store, transmit, and manipulate information. ICT are considered one of the key enabling technologies for industrial growth in Europe, providing infrastructures, technologies and systems for most of the economical sectors in EU, with a strong impact on society and individuals, that increasingly use and rely on them in their daily life.

The sector itself is responsible for some 5% of the European GDP, though the overall impact on economy is larger considering its enabling role in other sectors. Research and Innovation related to ICT accounts for some 25% of total business expenditure in R&D[333].

The Digital Agenda for Europe, one of the seven flagship initiatives of the Europe 2020 strategy, has been set to promote and support the deployment of these technologies in Europe.

The Digital agenda clearly identifies the key barriers for development of the ICT sector in EU: some are related to technology and market issues (investments in R&D, investment in networks, interoperability, fragmented digital markets, etc...) other concerns with ethical and societal issues. The latters include the need to improve ICT skills and *digital literacy* of EU professionals and citizens, address the increasing risks related to the abuse or misuse of ICT systems (cybercrime and online safety), and ensure the protection of fundamental rights regarding personal data and privacy and general consumer rights.

The dynamic development of the ICT has been reflected in an ample debate regarding the regulatory framework of the sector, followed by a series of changes and amendments in legislations in the last twenty years. The existing regulatory framework has been finalized in 2009. However, a full recast ("Connected Continent package") is currently under discussion with the scope to define a regulation that further harmonise and promote a single market for ICT in Europe and strengthen the attention to consumer rights (in particular addressing the so called *"net neutrality"* principle)[334]. The proposal has been approved by the Parliament and it is now waiting decision from the Council before it can be translated in law.

Voluntary measures, standards in particular, plays a fundamental role, both as an instrument to ensure implementation of regulation and as guideline for the plenty and diversified players (producers, service providers, retailers, authorities, etc.) that are operating in the ICT market.

Standards are enabling interoperability amongst components, devices, systems and allowing usage of ICT solutions in plenty of different applications. The Rolling Plan on ICT Standardisation provides a multi-annual overview of the needs for preliminary or complementary ICT standardisation[335].

The ETSI (European Telecommunications Standards Institute), together with CEN and CENELEC, have the mandate from the EC to develop standards (and harmonized standards)

[333] European Commission, ICT Research & Innovation.
http://ec.europa.eu/programmes/horizon2020/en/area/ict-research-innovation
[334] European Commission, Connected Continent legislative package.
http://ec.europa.eu/digital-agenda/en/connected-continent-legislative-package
[335] European Commission, The Rolling Plan on ICT Standardisation.
http://ec.europa.eu/enterprise/sectors/ict/standards/work-programme/index_en.htm

to support regulation in the ICT area, with a particular emphasis on ensuring safety of ICT devices and equipment.

Besides voluntary measures providing technical guidance to ICT industry and ICT professional, there are also training and learning initiatives targeted to users and consumers, on issues related to ethical behaviours (of service providers) and consumer rights. Relevant examples are the European Commission Code of EU Online Rights[336] (basic consumers rights in EU legislation related to the digital environment), the ongoing discussion about the creation of an EU trust mark scheme[337] providing confidence on quality and security of the online transaction (based on examples from some Member States), the safer internet programme of the European Commission[338] that led to the establishment of voluntary initiatives (code of conducts and best practice guidelines) from companies with respect to use of internet from kids and young people.

General sector regulation

The "Telecommunications Package" indicates the recast of the regulation for the ICT Sector made in 2009, which brought to a harmonized regulatory framework covering all electronic communications networks and services, including fixed-line voice telephony, mobile and broadband communications and cable and satellite television.

The overall aim of the framework is to encourage competition, improve the functioning of the market and guarantee basic user rights and high level of consumer protection.

The framework builds on the original regulation (2002) and consists of five Directives (including the two 2009 amendments) and two regulations[339]:

- The Framework Directive: main principles, objectives and procedures on electronic communications services and networks for national authorities, management of radio frequencies, numbering and addressing, rights of way, facility sharing.
- The Access Directive: pre-competitive obligations regarding access to and interconnection of networks on operators with significant market power
- The Authorisation Directive: general authorisation to facilitate entry in the market and reduce administrative burdens on operators;
- The Universal Service Directive: availability and affordability of basic electronic communications services and guaranteeing a set of basic rights for users and consumers
- The Directive on Privacy and Electronic Communications: rules for the protection of privacy and of personal data processed in relation to communications over public communication network

[336] European Commission, Code of EU Online Rights.
http://ec.europa.eu/digital-agenda/en/code-eu-online-rights
[337] European Commission, Action 17: Stakeholder platform for EU online trustmarks.
http://ec.europa.eu/digital-agenda/en/pillar-i-digital-single-market/action-17-stakeholder-platform-eu-online-trustmarks
[338] European Commission, Self-regulation for a Better Internet for Kids.
http://ec.europa.eu/digital-agenda/en/self-regulation-better-internet-kids
[339] European Commission, Telecoms Rules.
http://ec.europa.eu/digital-agenda/en/telecoms-rules

- The Regulation on Body of European Regulators for Electronic Communications (BEREC): defines BEREC, the body coordinating National Regulatory Authorities (NRA) in Member States in charge of the implementation of the framework.
- The Regulation on roaming on public mobile communications networks

These directives are related to procedures, rights and obligations regulating the functioning of communication networks, in order to ensure a fair competition, an open, transparent and non discriminatory access to the market for all telecom operators, service providers and end-users. Principles underlying the framework, with respect to the contracts and services provided include:

— right of choice
— quality of service
— safeguard of public and users interest
— transparency
— privacy

These principles are part of the concept, specific of the ICT sectors, of *"network neutrality"*, *"net neutrality"* (and also *"open internet"*[340]) defined by the framework directive as *"the ability for consumers to access and distribute information or run applications and services of their choice."*

A code of EU online rights has been published by the EC to provide guidance to consumers related to ICT services and online commerce activities. Principles and rights are set out with respect to access and use of online services, online commerce, conflict and dispute resolution[341].

Risk analysis
Request for general risk analysis measures to ensure security and integrity of public communications networks or publicly available electronic communications service are part of the overall ICT regulation. The main reference is given in article 13 of the framework directive, asking ICT operators to *"take appropriate technical and organisational measures to appropriately manage the risks posed to security of networks and services"*.

The Agency in charge of providing expertise and advice on risk and security issues is the European Network and Information Security Agency (ENISA).

Network and Information Security (NIS) to prevent cybercrime is a priority of the EU action. Besides legislative requirements, amongst the key documents published are the "*Communication on Critical Information Infrastructure protection (CIIP)*"[342] involving Member States and the private sector (2009), the "*European Strategy for a Better Internet for Children*"[343] (2012) and the European Strategy on Cyber security (2013)[344]. Activities are

[340] European Commission, Open Internet.
http://ec.europa.eu/digital-agenda/en/about-open-internet
[341] European Commission, Code Of EU Online Rights.
https://ec.europa.eu/digital-agenda/en/code-eu-online-rights
[342] European Commission, Policy on Critical Information Infrastructure Protection (CIIP).
http://ec.europa.eu/digital-agenda/en/news/policy-critical-information-infrastructure-protection-ciip
[343] European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions European Strategy for a Better Internet for Children, Brussels, 02.05.2012. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0196:FIN:EN:PDF

supported by ENISA and the Computer Emergency Response Team for the EU institutions (CERT-EU).

A proposal for a Directive on Network and Information Security (Cyber security Directive) is under discussion to harmonize and strengthen risk management measures on cyber security at Member State Level. In particular the EC propose to extend the obligation to report on significant cyber accidents to almost all kind of organizations (currently obligation is only for telecom operators and data controllers)[345].

Risk analysis and technical assessment of safety of devices and products used to provide communication services (such as equipment which uses the radio frequency spectrum) are mainly demanded to product specific directives. Amongst the most relevant for the ICT sector are:

- The Radio and Telecommunication Terminal Equipment (R&TTE) Directive (2014/53/EU), that covers products such as radio terminals, fixed network terminal equipments and other radio equipment's systems (and that will be replaced by the new Radio Equipment Directive that will enter into force in 2016)[346]
- The electromagnetic compatibility (EMC) Directive (2004/108/EC) that limits electromagnetic emissions and interferences of electric and electronic equipment, including components, products, fixed installations (will be replaced by the new EMC Directive that will enter into force in 2016)
- The Low Voltage Directive (2006/95/EC) covering health and safety aspects of all electrical equipment for use within certain voltage limits

These New Approach Directives set out safety objectives for the specific products concerned (via harmonized standards), requiring manufactures to comply with a conformity assessment procedure before placing the product on the market.

Data Protection Directive

The reference texts regarding data protection are the Privacy Directive 95/46/EC (processing and free movement of data) and the regulation (EC) No 45/2001 (processing and free movement of data by EU institutions and bodies) that stipulate general rules and obligations for "data controllers" (*the body processing the data*) and rights for "data subjects" *(people whose data are processed).* These are general purpose laws, applicable to data processed by automatic means as well as on traditional paper files, and affecting all kind of sectors (ICT, health services, public sector and finance, etc.).

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[344] European Commission, Communication on a Cybersecurity Strategy of the European Union – An Open, Safe and Secure Cyberspace.
http://ec.europa.eu/digital-agenda/en/news/communication-cybersecurity-strategy-european-union-%E2%80%93-open-safe-and-secure-cyberspace

[345] European Commission, Proposed Directive on Network and Information Security – frequently asked questions, 07.02.2013; European Parliament and the Council, Proposal for a Directive of 7 February 2013 concerning measures to ensure a high common level of network and information security across the Union, SWD(2013) 31 final, SWD(2013) 32 final, Brussels.
http://europa.eu/rapid/press-release_MEMO-13-71_en.htm and http://eeas.europa.eu/policies/eu-cyber-security/cybsec_directive_en.pdf

[346] European Commission, Radio and Telecommunications Terminal Equipment (R&TTE).
http://ec.europa.eu/enterprise/sectors/rtte/index_en.htm

The e-Privacy Directive (see following paragraph) further complement these norms with specific requirements for the ICT sector.

The EC Directive 95/46/EC requires Member States to set up an independent supervisory authority for data processing. The EC Regulation 45/2001 establishes the European Data Protection Supervisor (EDPS) with the responsibility to oversee the application of data protection rules by EU institutions and bodies.

Key guidelines and principles set out by these laws for the processing of data are: data quality, legitimacy, proportionality, rights to obtain information and access data, right to object, prohibition of processing of special categories of sensible data.

Requirements for data quality are indicative of the purposes of the legislation (art 6): "*personal data must be processed fairly and lawfully, and collected for specified, explicit and legitimate purposes. They must also be adequate, relevant and not excessive, accurate and, where necessary, kept up to date, must not be stored for longer than necessary and solely for the purposes for which they were collected".*

Risk analysis
National authorities define processing operations that might pose specific risks to the rights and freedoms of data subjects, and require for them notifications and prior checking of data controllers procedures. In some cases processing operations must also be declared to the EDPS.

The directive (article 25, 26) sets also rules regarding transfer of data to non-Member States, allowing the transfer only in case an adequate level of protection is ensured.

The data controller is responsible for compliance with the principles set out by Directive, including ensuring appropriate levels of confidentiality and security of data processing through appropriate risk analysis procedures. In particular art. 17 asks to: *"implement appropriate measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access"* and *"such measures shall ensure a level of security appropriate to the risks represented by the processing and the nature of the data to be protected".*

Exemptions are foreseen for public authorities for the purpose of the safeguarding of national security, public security, defence, crime and other overarching national interests. In order to further detail procedures for data processing by public authorities, the Council of the European Union adopted in 2008 the Framework Decision on the protection of personal data in the field of police and judicial cooperation in criminal matters.

Recently, the European Commission has proposed a "General Data Protection Regulation"[347] to reform legislation for data protection, harmonizing rules and procedures across MS and framework and strengthen citizens' rights (including issues related to easier access to personal data, privacy by design, right to be forgotten, explicit consent).

[347] European Parliament and of the Council, Proposal of 25 January 2012 for a regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data (general data protection regulation), SEC (2012) 72 final, SEC (2012) 73 final, Brussels.
http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

A full list of normative instruments and case law at EU level related to data protection is available on the dedicated webpage of DG Justice and Consumers of the European Commission[348]. At international level, references are provided by the work of OECD on the protection of privacy and transborder flows of personal data[349].

Privacy and data protection in electronic communications

The Directive 2002/58/EC (e-Privacy Directive) concerns the processing of personal data and the protection of privacy, translating into specific rules for the electronic communications sector the principles of the Directive 95/46/EC (Data Protection Directive). The main target are electronic communications services providers operating in public communications networks in the EU. The directive aims to regulate how ICT operators should handle and manage users' data, safeguard security and confidentiality, guarantee respect of rights of users and consumers. Main requirements are related to:

- **confidentiality of communications (and consent thereof)**
- **safeguard of security of networks and services**
- **data breach notifications**
- **traffic and location data (confidentiality, anonymity of)**
- **consent for unsolicited commercial communications (spam)**
- **inclusion in public directories (and consent thereof)**
- **calling-line identification (and related opt-out conditions)**
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Risk analysis

The law prescribes an obligation to assess and take security measures regarding data processing. Risks analysis is needed to identify appropriate measures to ensure security of networks and services as well as to notify users in case of *"a particular risk of a breach in the security network"* with respect to users' personal data (art 4). A further directive specifying the applicable measures regarding notification of personal data breaches under the e-Privacy directive has been published in 2013[350],

Directive 2002/58/EC introduces also indications for producers, manufactures and technology developers to take into account privacy issues during the design phase of the services or product (provided that devices remains compliant with safety obligations and conformity assessment set in new approach directives) *"It may therefore be necessary to adopt measures requiring manufacturers of certain types of equipment used for electronic communications services to construct their product in such a way as to incorporate safeguards to ensure that the personal data and privacy of the user and subscriber are protected."*

[348] European Commission, DG Justice and Consumer.
http://ec.europa.eu/justice/data-protection/law/index_en.htm

[349] OECD, revised Guidelines on the Protection of Privacy and Transborder Flows of Personal Data, amended on 11 July 2013 by C(2013)79.
http://www.oecd.org/sti/ieconomy/privacy.htm

[350] European Commission, REGULATION (EU) no 611/2013 of 24 June 2013 on the measures applicable to the notification of personal data breaches under Directive 2002/58/EC of the European Parliament and of the Council on privacy and electronic communications, Brussels, 26.06.2013.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:173:0002:0008:en:PDF

Data Retention Directive

The Directive 2006/24/EC[351] on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks (amending Directive 2002/58/EC) obliges operators in the ICT field to retain traffic, location data and other information for a certain period, for national security reasons (investigation, detection and prosecution of crime and terrorism). Data can be accessed by authorities under permission granted by a court. Though data retained are limited (do not include contents) they might allow for tracking identity of end-users of the communication.

Risk analysis

The Directive requires that appropriate technical and organizational measures are put in place regarding handling of data (access, storage, destruction) to ensure data protection and data security, in particular regarding privacy and confidentiality of data.

In 2014 the European Court of Justice declared invalid the Directive, referring to the principle of proportionality as well as the Charter of Fundamental Rights, and privacy as a fundamental right of EU Citizens. This decision open up a period of legal uncertainty[352].

Privacy by Design

The Digital Agenda for Europe (2009) envisages the wide application of the "Privacy by Design" principle for relevant ICT technologies in order to support protection of fundamental rights at EU levels. So far, specific policy actions have been promoted regarding Radio Frequency Identification Devices (RFID), increasingly used in many sectors to store and handle information, including personal data.

In 2009, the European Commission issued a mandate to CEN in order to develop standards to improve data protection and consumer information with respect to the use of RFID. Two documents have been published so far: the *EN 16570:2014 Information technology (Notification of RFID)*, providing guidelines for information sign and additional information to be provided by operators of RFID application systems[353] and the EU-norm *"Privacy and Data Protection Impact Assessment Framework for RFID Applications"* providing guidelines to industry in order to perform Privacy Impact assessment on their products [354].

[351] European Commission, Data Retention.
http://ec.europa.eu/dgs/home-affairs/what-we-do/policies/police-cooperation/data-retention/index_en.htm

[352] Court of Justice of the European Union, Judgment in Joined Cases C-293/12 and C-594/12 Digital Rights Ireland and Seitlinger and Others, Luxembourg, 08.04.2014.
http://curia.europa.eu/jcms/upload/docs/application/pdf/2014-04/cp140054en.pdf

[353] European Committee for Standardization, Information technology - Notification of RFID - The information sign and additional information to be provided by operators of RFID application systems, Brussels, 14.05.2014.
http://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:38350,6206&cs=1BAE0547EB314F2AF0D24EF8AADCD6A0E

[354] European Commission, Privacy and Data Protection Impact Assessment Framework for RFID Applications of 12 January 2011, Brussels.
http://ec.europa.eu/digital-agenda/news/privacy-and-data-protection-impact-assessment-framework-rfid-applications

BIOTECHNOLOGIES (GMOS)

Biotechnologies are broadly defined as *"The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services"*. Biotechnology techniques include engineering and processing of: DNA/RNA, proteins and other molecules, cell and tissue culture, gene and RNA vectors, and they include areas such as bioinformatics and bionanotechnologies[355].

Biotechnologies are fueling one of the most relevant and innovative areas in Europe. Considering data reported by Horizon 2020 and the European Association for Bioindustries (EuropaBio), the bioeconomy is generating (2011) some 20 million jobs, 4000 biotech companies and an investment in Research and Development of about 6 billion euro/year.

Biotechnology applications are generally broken down into three main subdisciplines[356]:

- Red biotech: using living organism and recombinant technologies to produce medicinal and healthcare products;
- Green (or agricolture) biotech: application of various "plant breeding" techniques, in particular genetical modification, to develop novel agricoltural products;
- White (or industrial) biotech: using enzymes and micro-organisms to make bio-based products and develop new industrial processes, including new chemicals, food and feed, textiles, fuels, etc.

Genetic modification (genetic engineering) is defined as *"the manipulation of the genetic material of an organism to produce desired traits"*[357]. An organism that is generated through genetic engineering is considered to be a genetically modified organism (GMO).

GM and GMOs have a relevant impact on all areas of biotechnologies above, including research (e.g. GM animals for testing), green biotech (e.g. genetically modified crops), white biotech (e.g. GM crops for the production of biofuels), and red biotech (e.g. the development of insuline).

The European policy strategy for life sciences and biotechnology, including GMOs, has been originally set in a communication of the European Commission dated 2002[358]. Policy actions to support R&I in biotechnologies have been included in European framework programmes and other policy tools, with respect to the different areas of application (healthcare, agrifood, resource efficiency and environment, etc). Within Horizon 2020 biotechnologies are classified as one of Key Enabling Technologies with a cross-cutting impact on all industrial sectors.

General sector regulation

The regulatory framework for GMOs in Europe consists of a set of legislations providing requirements for notification, authorization, inspection, monitoring and control procedures of products using in various forms GMOs, with the overarching scope of protecting human

[355] OECD Glossary of Statistical terms.
http://stats.oecd.org/glossary/
[356] EuropaBio.
http://www.europabio.org/what-biotechnology
[357] OECD Glossary of Statistical terms.
http://stats.oecd.org/glossary/
[358] European Commission, Biotechnology – Strategy for Europe on Life Sciences and Biotechnology.
http://ec.europa.eu/food/food/biotechnology/strategy/index_en.htm

health, animals and the environment.

Main legislative acts are:

- Directive 2001/18/EC on the deliberate release into the environment of GMOs: harmonization (across Member States) of principles, objectives and procedures to protect human health and the environment for both placing on the market (importing, manufacturing and marketing) and experimental use of GMOs
- Regulation EC No. 1829/2003 on genetically modified food and feed: sets out safety assessment and authorization procedures for food and feeds products *"containing, consisting of or produced from GMOs*"
- Regulation (EC) No 1830/2003: concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs
- Regulation (EC) No 1946/2003 on transboundary movements of GMOs: sets out rules for the export of GMOs, ensuring harmonization with the Cartagena Protocol on Biosafety.

Other acts related to specific products and issues related to GMOs include:

- Directive 2002/53/EC: common catalogue of varieties of agricultural plant species
- Directive 2002/55/EC: the marketing of vegetable seed
- Directive 2009/41/EC: the contained use of genetically modified microorganisms.
- Regulation (EU) No 619/2011: methods of sampling and analysis for the official control of feed as regards presence of GM material
- Regulation EC 65/2004: unique identifiers for traceability of GMOs
- Regulation EC 619/2011: amending Directive 2001/18/EC in order to harmonize the implementation of the zero-tolerance policy on non-authorized genetically modified (GM) material in feed

Depending from the application considered, the notification and authorization process for GMOs is carried out by Member States (competent authorities) or at EU level[359]. The relevant national committees and the European Group on Ethics in Science and New Technologies might be consulted regarding ethical implications of GMOs.

Different uses of GMOs are covered by these legislations, including:

- the research and development of GMOs
- introduction and deliberate release into the environment (for food, feeds, industrial processing, etc.)
- cultivation and seed production
- the whole agro-food chain (e.g. food and feed for humans and animals, food quality treatments, etc)

Directive 2001/18/EC excludes human being by the regulatory definition of GMOs[360]. The use of GMOs in pharmaceuticals (red biotech) is generally covered by the legislation on

[359] For food and feed regulation EC No. 1829/2003 establishes that EFSA is responsible for scientific evaluation of risks

[360] The following definition is provided: *"genetically modified organism (GMO). means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"*

medicinal products for human use, requiring detailed risk assessment and pre-market authorization procedures[361].

However, directive 2001/18/EC provides that authorizations granted under other legislative instruments (e.g. medicinal products) shall ensure that GMOs complies with essential requirements of this directive (in particular the need for an environmental risk assessment).

There are several bodies and agencies at EU and international level providing guidance on risk analysis and regulatory provisions for GMOs. These include the European Food Safety Agency (in particular the GMO Panel), the Joint Research Council (hosting the European Union Reference Laboratory for GM Food and Feed)[362], the European Commission DG Health and Consumers[363], the FAO GM Food Platform[364] and the BioSafety Clearing House, established by the Cartagena Protocol[365].

Risk analysis

The EU legislative framework for GMOs, whose drafting and application is based on the precautionary principle, is considered as one of the most comprehensive and stringent in the world. The placing on the EU market of GMOs requires authorization on a case-by case basis, preparation of detailed environmental risks assessment and specific product safety assessment.

Principles for risk analysis include:

- Extensive research and development in ecosystem prior to marketing
- Case by case Environmental Risk Assessment (ERA), based on the precautionary principle and taking in due account long term impacts of GMOs. The ERA must include: information on the GMO, conditions of release and the receiving environment, interaction between the GMOs and the environment, information on monitoring, control, waste treatment and emergency response plans. The ERA is harmonized with the methodology provided in the Cartagena Protocol on Biosafety
- Pre market notification and authorization based on a technical dossier including data and information on: purpose and scope of the product, data and analysis related to the ERA, safety measures, condition for placing on the market, labeling and packaging measures, (safety) monitoring measures
- Labeling and traceability of products containing or using GMOs[366]
- Mandatory information/notification of new uses and risks, and post market environmental monitoring of health and environmental risks of GMOs
- Public information of the GMOs authorized at EU level, including information on

[361] European Parliament and of the Council, Regulation (EC) No 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Brussels, OJ L 136, 30.4.2004.
http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004R0726
[362] European Commission, Joint Research Council.
https://ec.europa.eu/jrc/
[363] European Commission, Genetically Modified Food and Feed.
http://ec.europa.eu/food/food/biotechnology/index_en.htm
[364] FAO GM Foods Platform.
http://www.fao.org/food/food-safety-quality/gm-foods-platform/en/
[365] The Biosafety Clearing-House (BCH).
https://bch.cbd.int/
[366] Reg. 1829/2003 introduces a threshold level for labelling of food and feed: labelling is required for products which *"contain, consist of, or are produced from GMOs in a proportion higher than 0.9% of the food ingredients (or feed)"*

conditions of use and risk analysis (e.g. a register is regularly updated on a dedicated EC webpage[367])

- Analysis of ethical issues and socio-economical impacts (a report on the matter is regularly prepared by the EC)

Directive 2001/18/EC includes a safeguard clause (art 23) that allows member states to provisionally restrict or prohibit the use or sale of GMOs on their territory, if new scientific knowledge has become available providing indications that the product poses risks to human health or the environment. The Member State have to submit a review of the environmental risk assessment for the product concerned to the Commission and the other Member States supporting the request to apply restrictions. A number of Member States are currently using this clause on specific GMOs event.

The six steps in the analysis of Environmental Risk Assessment of a GMO (extract from EFSA scientific opinion on ERA of GMOs) are[368]:

1. **Problem formulation** (including hazard identification)
2. **Hazard characterization** (qualitative and/or quantitative evaluation of environmental harm)
3. **Exposure characterization** (evaluate likelihood of adverse effects, and estimate the exposure quantitatively)
4. **Risk characterization** (combining the magnitude of the consequences of a hazard and the likelihood that the consequences occur)
5. **Risk management strategies** (identify strategies to reduce the identified risks associated with the GM plant to a level of no concern and to consider defined areas of uncertainty).
6. **Overall risk evaluation and conclusions** (provide informed qualitative and, if possible, quantitative guidance to risk managers).

An overall risk management evaluation, including Post Market Environmental Monitoring (PMEM), follows the ERA. Risk management decisions might require additional ERA activities.

[367] European Commission, EU Register of authorized GMOs. http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

[368] Extract (pg 18 onward) from the Scientific Opinion, Guidance on the environmental risk assessment of genetically modified plants, EFSA Panel on Genetically Modified Organisms (GMO), EFSA Journal 2010;8(11):1879 - http://www.efsa.europa.eu/it/efsajournal/doc/1879.pdf

ANNEX: LIST OF LEGISLATIONS

An indicative (and partial) list of legislations related to the contents of the report, and relevant research and innovation and manufacturing activities, is hereafter reported.

Chemicals:

- **Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**
- **Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures**
- Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the **control of major-accident hazards involving dangerous substances**, amending and subsequently repealing Council Directive 96/82/EC.

Cosmetics

- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 **on cosmetic products**

Data Protection

- **Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data**
- Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the **processing of personal data by the institutions and bodies of the Community and on the free movement of such data**.
- **Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (privacy and electronic communications)**

Energy

- **Directive 2010/31/EU of the European Parliament and of the Council of 19 May 2010 on the energy performance of buildings.**
- **Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products**
- **Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources**
- **Directive 2006/32/EC of the European Parliament and of the Council of 5 April 2006 on energy end-use efficiency and energy services and repealing Council Directive 93/76/EEC**

Environment, industry plants/installations

- Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards **priority substances in the field of water policy**.

— Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2011/92/EU on the **assessment of the effects of certain public and private projects on the environment**
— Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the **control of major-accident hazards involving dangerous substances**, amending and subsequently repealing Council Directive 96/82/EC
— Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards **priority substances in the field of water policy**
— Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 **on industrial emissions** (integrated pollution prevention and control)

Food and Agrifood

— **Regulation (E**C) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the **general principles and requirements of food law**, establishing the European Food SafetyAuthority and laying down procedures in matters of food safety
— Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 **on food additives**
— Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on **materials and articles intended to come into contact with food**
— Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the **provision of food information to consumers**
— Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning **the placing of plant protection products on the market**
— Regulation (EU) No 528/2012 of the European Parliament and of the Council of May 2012 concerning the **making available on the market and use of biocidal products**

GMOs

— **Directive 2001/18/EC of the European Parliament and of the Council of of 12 March 2001 on the deliberate release into the environment of genetically modified organisms**
— **Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed**
— **Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms**
— **Regulation (EC) No 1946/2003 of 15 July 2003 of the European Parliament and of the Council on transboundary movement of genetically modified organisms.**

Information and Communication Technologies (ICT)

— Directive 2002/21/EC of the **European Parliament and of the Council** of 7 March 2002 on a **common regulatory framework for electronic communications networks and services (Framework Directive)**, as amended by Directive 2009/140/EC and Regulation 544/2009
— Directive 2002/19/EC of the **European Parliament and of the Council** of 7 March 2002 on **access to, and interconnection of, electronic communications networks and associated facilities** (Access Directive), as amended by Directive 2009/140/EC

— Directive 2002/20/EC of the **European Parliament and of the Council** of 7 March 2002 on the **authorisation of electronic communications networks and services** (Authorisation Directive), as amended by Directive 2009/140/EC)
— Directive 2002/22/EC of the **European Parliament and of the Council** of 7 March 2002 on **universal service and users' rights relating to electronic communications networks and services** (Universal Service Directive), as amended by Directive 2009/136/EC
— **Regulation (EU) No 531/2012 of the European Parliament and of the Council of 13 June 2012 on roaming on public mobile communications networks within the Union**
— **Regulation (EC) No 1211/2009 of the European Parliament and of the Council of 25 November 2009 establishing the Body of European Regulators for Electronic Communications (BEREC)**
— Directive 2006/95/EC of the **European Parliament and of the Council** of 12 December 2006 on the harmonisation of the laws of Member States relating to **electrical equipment designed for use within certain voltage limits**
— Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the **restriction of the use of certain hazardous substances in electrical and electronic equipment**

Horizon 2020

— Regulation (EU) No 1291/2013 **of the European Parliament and of the Council** of 11 December 2013 **establishing Horizon 2020** - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC
— Regulation (EU) No 1290/2013 **of the European Parliament and of the Council** of 11 December 2013 laying down the **rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)**" and repealing Regulation (EC) No 1906/2006

Liability

— **Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products**
— **Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage**

Medicinal and Veterinary products

— Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the **Community code relating to medicinal products for human use**
— Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of **good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use** ("the GMP Directive)
— Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the **authorisation and**

supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

- Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for **good clinical practice** as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products" (**Good Clinical Practice**)
- Regulation No 536/2014 of the European Parliament and of the Council on **clinical trials on medicinal products for human use**, and repealing Directive 2001/20/EC
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the **protection of animals used for scientific purpose**
- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to **veterinary medicinal products**

Medical devices

- **Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)**
- **Council Directive 93/42/EEC on Medical Devices (MDD) (1993)**
- **Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)**

Occupational Health and Safety

- Council Directive 89/391/EEC of 12 June 1989 on **the introduction of measures to encourage improvements in the safety and health of workers at work**
- Council Directive 98/24/EC of 7 April 1998 on **the protection of the health and safety of workers from the risks related to chemical agents at work**

Transport:

- **Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor**

17 ANNEXES

17.1 QUESTIONNAIRE

Questionnaire for the purpose of preparing country studies
(Task 3.1 - Legal and regulatory aspects[369])

Guidelines for partners:

In order to identify legal frameworks that currently guide and/or constrain ethical procedures within research and research assessment in the assigned countries please answer questions listed under each of the 18 domains. Please study existing legislation, regulations as well as soft-law instruments and codes of conduct.

When answering the specific questions pay attention to the history, motivation, formulation, and implementation of the legislation and broader frameworks identifying:

- creators of the legislation, mandate, regulations, etc.
- aims of the legislation, mandate, regulations, etc.
- who is targeted by the frameworks, with special consideration paid to whether the frameworks govern the ethical activity of bodies or the implementation of innovations
- themes, principles, ethical considerations which are explicitly identified. If possible study the "regulatory impact assessment" document[370] of each legal act - does it mention (ethical) principles that guided the adoption of the framework?

In addition, for each of the domains (except no. 1), please provide a list of legislation, regulations, soft-law instruments and ethical codes relevant for ethics assessment. Please provide translations of the names of the acts and most important provisions relevant to ethics assessment that you refer to in the text.

List of domains:

1. **National legal system – basic information**

   Please describe briefly basic features of the national legal system: What types of legal acts exist? Which institutions adopt them? Who do they target? What is their hierarchy? Is a *regulatory impact assessment* performed in the case of all legal acts? If yes, what is assessed?

2. **Scientific freedom**

   - What is the status of *scientific freedom* and related concepts such as *academic freedom* or *freedom of research*? Are they referred to in the Constitution? If yes, please quote and translate the relevant provisions. Does the law specify circumstances when scientific freedom can be limited? If yes, please give details.

[369] Task 3.1 explores legal and regulatory frameworks (including soft-law instruments) relevant for ethics assessment. Partners are asked to provide information about national legal systems.
[370] RIA is a document created before a new regulation is introduced. RIAs are produced in many countries, although their scope, content, role and influence on policy making vary.

- What are the most important decisions of highest courts regarding scientific freedom? Please briefly describe the key statements of those decisions.
- Are there provisions explicitly banning certain types of research or excluding it from receiving public funding? What types of research are these?
- What types of research require permissions or opinions of ethical committees (for example (medical) research involving humans, animal experimentation etc.)?

3. Research and innovation– basic features of regulatory landscape

- Is there a definition of research for normative purposes? If yes, please quote and answer the following questions:
    - Who produced it?
    - Does it exist only for medical research? For clinical trials? For public health? Is there a different or any definition of research for human and social sciences?
    - Does the same definition apply for health research regardless of it being medical, clinical, or for social sciences?
    - Does it apply only if it involves human participants? Does the same definition apply to research involving humans and animals?
- What are the most important provisions relevant to research included in the Constitution?[371]
- Has a "national research act" been adopted?[372] If yes what types of research does it cover? What ethical principles does it refer to? Or are provisions on research spread among different legal acts and regulations? What are these legal acts?
- Are there any other sources of soft law and/or ethical guidelines for research (such as a national bioethics committee, professional associations)?
    - If yes, what is their role?
    - Are they regulated?
    - Who established them?
- Is there an obligation to publish research results funded by public sources?
- Are there special provisions for research conducted out of national borders? If yes, please give details.
- Are there special provisions for research conducted with least developed countries? If yes, please give details.
- Are there any sanctions foreseen for research carried out outside the legal framework or without the pertinent ethical clearance?
    - If yes, what are they?
    - Who and how enforces the sanctions?
- In addition, is there a definition/definitions of "innovation" for normative purposes? If yes, please quote and answer the following questions:
    - Who produced it?
    - In which fields is it applied?

4. **The right to enjoy the benefits of scientific progress and its applications** (*Article 15, International Covenant on Economic, Social and Cultural Rights*)

[371] E.g. in Poland freedom to conduct research is guaranteed in Article 73 of the Constitution on one hand, on the other there is Article 39 which prohibits scientific experimentation without consent.
[372] E.g. in the US the National Legal Ac was adopted in 1974, partly in response to the Tuskegee syphilis study.

- Is the right to enjoy the benefits of scientific progress and its applications referred to in any national legal acts, regulation, guidelines or soft law instrument? If yes, please give details. Have a look at the country reports submitted to the Committee on Economic, Social and Cultural Rights,[373] i.e. the part that refers to article 15 – does the report mention steps taken to safeguard this particular right?)

5. Scientific integrity: codes of conduct and sanctions for scientific misconduct

- Are there any binding laws and regulations on scientific integrity? If yes, please give details. What are the most important codes of conduct and soft law instruments including self-regulation established to safeguard scientific integrity? Please refer to both documents of general nature as well as those established for a specific discipline or profession.
- What types of scientific misconduct are penalized? What kind of sanctions can be imposed? Is, for example, plagiarism, falsification or fabrication penalized with criminal, administrative or disciplinary sanctions? Does it rely on self-regulation?
- Who is dealing with cases of scientific misconduct (courts, ethics committees, etc.)?

6. Impact assessments, risk analysis and precautionary principle

- To what extent does law regulate issues of impact assessment and risk analysis? What is the legislation on (environmental, ecological, etc.) risk?
- In what fields of law relevant to research and innovation is there an obligation for an impact assessment or risk analysis of any kind to be carried out?
    - When is an environmental and/or social impact assessment a legal requirement?
    - What national laws and regulations apply?
- Are there any other impact assessments required by the law or recommended (e.g. privacy impact assessment, privacy risk analysis, technical assessment)? If yes, please give details.
- Is precautionary principle referred to in any national laws relevant to research and innovation? If yes,
    - What is its role?
    - Please provide a list of relevant laws documents and translations of relevant provisions.

7. International instruments in national law

- What international conventions relevant to ethics assessment has the country signed and/or ratified? For example: has the country ratified the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine and any of the additional protocols? If yes, what were the legal

[373] These can be found at the Office of the High Commissioner for Human Rights: http://tbinternet.ohchr.org/_layouts/treatybodyexternal/TBSearch.aspx?Lang=en&TreatyID=9&DocTypeID=29

amendments to national laws that the ratification has brought? Has the state made any reservations or declarations to the Convention relevant for the conduct of research and innovation?

- Do the national frameworks relevant to ethics assessment refer to international instruments (e.g. Declaration of Helsinki, CIOMS guidelines, 2005 Universal Declaration of Bioethics and Human Rights, Universal Declaration on Human Rights, 1974 Recommendation on the Status of Scientific Researchers, 1999 Declaration on Science and the Use of Scientific Knowledge, Belmont Report, any WHO guidelines (UNAIDS, etc.)? If yes, please give details.

8. Laws on assessors

- The establishment of which type of ethics committees is set by law [e.g. national or regional (policy oriented) ethics committees, research ethics committees: at hospitals, at universities, at research institutes]? What is the legislation pertaining to ethics committees? In case there is no binding legal obligation to set up ethics committees, are there guidelines or soft law instruments that recommend setting up ethics committees?

- What types of research do the committees oversee:
    - all research or just specific types?
        - e.g. medical research?
        - clinical trials?
        - research in social sciences?
        - behavioral research?
        - research in natural sciences?
        - research involving animals?
        - other areas?
    - Do the committees review both the scientific and the ethical aspects of the research?

- Who are members of the committee?
    - Is there a profile or criteria to appoint the chair?
    - How are the members appointed?
    - How long is their term?
    - Do they meet regularly?
    - Can they be released from their duties?
    - If yes, in what situations?
    - How are the committees funded? If so, by whom?
    - Does the committee charge fees?
    - Do members receive compensation?
    - Do members serve in their professional or individual capacity?

- Is there any surveillance of their work? Are they accountable to any authority? What are the parameters they should use to make their evaluation? If there are parameters, how are they established? By law? Or national guidelines? Or otherwise?

- What qualifications should members of the committees have? Is there a legal requirement (or included in SOP/guidelines or is a standard practice) to:
    - Include people trained in bioethics and/or research ethics?
    - To have training once they become members? If yes, what kind of training is this?
    - To update their training in the domains of bioethics and/or research ethics?
- What is the procedure to obtain an opinion or permission? Is there a possibility to appeal the decision? If yes, who can appeal the decision?

- Is it obligatory to obtain an opinion or permission? Is the opinion binding? What are the consequences of a negative ethical review?

- Is there any legislation that foresees the establishment and regulates the work of funding agencies? If yes: give the details. Is there a legal obligation for the funding agency to have a research ethics committee? Is there any legal obligation to have an ethical review of the proposal?

- Are there ad hoc ethics review committees in the country? Are these types of committees regulated? If yes, please give details. Is there any surveillance of their work? Are they accountable to any authority? What are the parameters they should use to make their evaluation?

- As regards ethics committees in industry – is there a legal obligation to establish ethics committees at companies that deal with research and innovation? Is it recommended in any soft law documents or guidelines? What is the role of such committees? What is the normative basis for their activities?

- Are there any other requirements, different from a requirement to have ethics committees, that apply to the organizations/institutions mentioned above (universities, hospitals, research institutes, funding agencies, etc.) and may be relevant to ethics assessment, for example a requirement to have an office for scientific integrity or an ethics code for research?

- Is there any legislation pertaining to any other national/government or government funded agencies that engage in ethics assessment? If so, what?

9. Corporate Social Responsibility Strategy

- Which kinds of demands are put on business to be ethical, e.g. is there a requirement for industry to have a CSR strategy or to have an ethics code and/or social impact statement? Are companies obliged to provide information on environmental and/or social performances?
- Has the country developed a National Action Plan on Business & Human Rights?[374]

[374] OHCHR, State National Action Plans; UN and OHCHR, The UN Guiding Principles on Business and Human Rights, 2011.

10. Research involving humans:

- What laws governs different types of research involving humans (e.g. medical research, clinical trials, behavioral and social sciences research etc.)? Are there specific national legal acts that govern different types of research or are rules governing research included in more general laws? Do the laws distinguish different groups of participants (e.g. healthy and sick study participants, adults and minors etc.) and research that benefits the individuals and research that benefits a group?

- Is there an explicit obligation that the interests and welfare of the human being participating in research should prevail over the interest of society or science (the so- called principle of human primacy[375])? Please quote relevant provisions.

- Is ethical review of all research involving humans a statutory requirement or is the requirement limited to some types of research, e.g. medical research, clinical trials?

- Is there a legal requirement to obtain an informed consent from research participants in the case of all types of research involving humans?

    - What type of information should be provided to the research subjects? Is there any legal or soft law document with specific requirement of what should be included in the informed consent? If yes, please give details.

    - Do the same rules on informed consent apply to research conducted on the person as to research on personal data? Please give details.

    - Who should provide the research subject with information?

    - Is there a requirement for consent to be a continuing process?

    - Is there a concept of presumed or broad consent? If yes how are presumed or broad consent defined? How is the issue of future uses of data or samples dealt with?

    - Are there procedures addressing "substituted judgment" standards?

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http://www.ohchr.org/EN/Issues/Business/Pages/NationalActionPlans.aspx, http://ec.europa.eu/enterprise/policies/sustainable-business/corporate-social-responsibility/human-rights/index_en.htm

[375] For a reference point see: Article 3 of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, article 2 (1) of the Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products, Brussels; and articles 4 (i) and 5 (h) of the Clinical Trials Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, Brussels, 01.05.2011.

- Do informed consent standards pertain specifically to individual consent?

- Does the law make it explicit that:
  - the research participant can withdraw from the research at any time?
  - there is a need to balance risk and benefits?

- Can research participants be compensated?

- Does the law specify what conditions need to be fulfilled for research involving humans to be undertaken (e.g. ethical review, balancing risk and benefits etc.)?[376] Does it apply to all types of research?

- *Minors*: Are there any, and if so, what are the specific rules and requirements of research on minors? Who has to give the consent? Should both parents give their consent, if they share custody? In emergency cases can research on minors be performed without the consent? Does the child have to be consulted? Is there a requirement for benefit of the child? Is research of no direct benefit (the so-called non-therapeutic research) permitted? Please add any relevant missing information?

- *Adults unable to give consent*: Are there any, and if so, what are the specific rules and requirements for research on incapacitated adults or other adult persons not able to give informed consent?
  - Who gives the consent?
  - Is there a requirement for benefit of the participant? Is research of no direct benefit (the so-called non-therapeutic research) permitted?
  - Can research without consent be performed in emergency situations? Is it possible in exceptional circumstances to conduct research that does not have the potential to produce results of direct benefit to the person concerned?
  - Is it allowed for incarcerated persons? If so, what are the provisions?

- Are there any laws or guidelines pertaining specifically to safety monitoring?
  - Is there an obligation to report on adverse effects during clinical trials, research, any other circumstance?

11. Research involving animals

- Is animal welfare or animal protection a constitutional goal? If yes, please give details. How is animal defined for normative purposes?
- Is all scientific work involving animals subject to ethical review? If yes, what national laws and regulations apply? If no, which kinds of scientific work involving animals are selected for review? In case there is no requirement for

[376] Please compare the list of conditions to Articles 3 (2) of the Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, Brussels, 01.05.2011.

an ethics review are there alternative mechanisms e.g. at universities, research organizations?
- At what point is the review carried out?
- Who carries out the ethical review? What is the composition of a relevant committee?
- Do members of the ethical review process receive any training? What kind of training is this?
- What is the scope of ethical review and what aspects are covered? Are there particular guidelines for carrying out the review and checklists that have to be considered?
- Is there an on-going ethical review after the initial permission for the work is granted?
- Are the same review procedures used for all scientific work involving animals or are some uses subject to special review? What are the criteria for a special review?
- Are animal experiments prohibited for certain research purposes? If yes, please give details.
- Are any specific procedures explicitly prohibited? If yes, please give details.

12. Biobanking

- Is there a definition of a bio bank for regulatory purposes? If yes, please give the definition and details. Are all types of bio banks subject of regulation?
- Is there a specific legal act that covers biobanks or are provisions on biobanks integrated into other broader laws or regulations? What are their ethical and legal guiding principles?
- Are intellectual property rights to biological material regulated? If yes, how?
- Is the issue of the informed consent regulated? (Please pay special attention to the question of consent of members of vulnerable groups) If yes, how?
- Are there any means to guarantee the protection of privacy and personal data of donors? If yes, what are they?
- Are there any safeguards against discrimination and/or stigmatization? If yes, what are they?
- Is the issue of benefits sharing addressed? If yes, please give details.
- Are biobanks required to inform individuals about important findings? Are there any provisions for incidental findings? If yes, please give details.
- Is there a requirement for an in-house ethics assessment body? Are they regulated? If so, how?
- Are there regulations pertaining to conducting research using human tissues? If so, what condition have to be fulfilled? How are they derived?
- Is the post-mortem use of samples regulated? If yes, how?

13. Embryo and stem cell research, human embryonic stem cell research

- Is embryo research allowed and in what terms and conditions? If yes, which body is in charge of the approval of embryo research (ethics review)?
- What (ethical) principles do the laws that apply to embryo research refer to?
- Does the law provide a definition of embryo? If yes, please give details.
- What are the formal and legal requirements for embryo research approval?

- Is the creation of embryos for research purposes or stem cell procurement allowed in the country, if yes at what condition?
- Does the law foresee informed consent procedures from individuals involved in embryo donation for research? Please describe them.
- Is financial remuneration allowed? In what terms?

14. Genetic testing

- Is genetic testing regulated? Is there a specific oversight of commercial genetic testing? If yes, please give details.
- Are there any safeguards against genetic discrimination and stigmatization? If yes, what are they?
- Is there a legal obligation to communicate genetic research results? If yes, to whom are the results communicated? Are there any ethical guidelines about this specific item? If yes, please give details.
- Are there provisions on the "right not to know"? If yes, please give details.
- What protection is genetic data granted?
- Is genetic counseling required? Is it considered in the law? How is it organized? Who is responsible for carrying it out?
- Are there provisions on consent, disclosure, privacy and confidentiality? IF so, what are they? How is genetic testing on minors, incapable persons and those with reduced capacity regulated?
- Are there rules on the storage of personal data? If so, elaborate.
- Can the employer/ insurance company/ the court request genetic tests to be performed? If yes, give details of how it is regulated or not.

15. Privacy and data protection

- What are the rules on the processing of personal data for research purposes? Please pay special attention to medical research. When is the processing of sensitive personal data for the purpose of research legal? What conditions have to be met?
- How is the issue of consent for the processing of personal data for the purpose of research regulated? How was the data protection directive implemented with regard to the use of personal data for research purposes?
- What are the obligations of data controllers and data processors in R&I aimed at safeguarding the protection of personal data of individuals? What are the rights of data subjects?
- Is the concept of privacy by design referred to or implied in any regulation? Are technology designers and producers obliged to comply with requirements of privacy and personal data protection, e.g. by implementing privacy enhancing technologies, privacy by default settings or other tools to enable users to better protect their personal data (e.g. access controls, encryption)? Is there a requirement to design and construct new technologies or introduce new solutions or innovation in a way that would minimize the amount of personal data processed? Is there such a requirement for a specific technological context

(e.g. RFID technology, social networks, behavioral advertisement, etc.)?[377] At what stage should the safeguards be implemented?

- According to Article 14.3 of the Directive on privacy and electronic communications „Where required measures may be adopted to ensure that terminal equipment is constructed in a way that is compatible with the right of users to protect and control the use of their personal data" – how has this provision been implemented?

16. Dual Use

- Is there a specific regime on the control of dual-use items that can be used for both civil and military purposes? What laws apply? What are the soft law instruments or guidelines in this field? Has the state implemented the Chemical Weapons Convention and the Biological Weapons Conventions?
- Are there specific rules or guidelines on dual use research? If yes, what are they? Is it referred to in ethical codes or codes of good practice? What safeguards are to be taken by researchers? Is there a review board for the dual use research? In what contexts is the issue of biological security addressed? What are the rules of publication of dual use research results - are there any limitations on publishing research results that has the potential to be misused?
- Is there an obligation for researchers or institutions to alert the coordinating authority about the potentially serious threat?

17. Vulnerable participants

- Are some groups granted special protection or cannot participate in some kinds of research (e.g. pregnant women in medical experiments, detained persons, etc.)? If yes, please give details. Please pay attention to binding provisions as well as soft laws or guidelines.

18. **Other frameworks and emerging issues**

- Please describe any other national frameworks that relate to, or have consequences for ethical assessment or research and innovation but have not been yet mentioned (e.g. regarding novel food, chemicals, engineering, GMOs, synthetic biology, nanotechnology, convergence of technologies etc.).

- Please identify ongoing national developments in particular with reference to emerging issues in bioethics and in the regulation of emerging technologies. What novel technologies have presented need for ethical assessment?

- Please identify areas of historical contention within research ethical assessment that have emerged in social/cultural/political debate? Which media is involved in these debates – news/entertainment/political platforms/academic debates? How do they advance/constrain ethical assessment practices?

- Identify actors within the field of research ethical assessment, such as non-profits, advocacy groups, religious organizations

- Are there any issues regarding ethical assessment that are framed as unique to the region/population involved? Are there any explicit value systems that are regularly invoked?

17.2 LISTS OF NATIONAL INSTRUMENTS

Attached